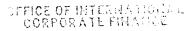


## RECEIVED

2005 MAR -8 A 9 C3



Securities and Exchange Commission Judiciary Plaza 450 Fifth Street Washington DC 20549 3 March 2005



Dear Sir/Madam

## Reference: 12g3-2(b) File number 82-34831

Please find attached filings required under the 12g3-2(b) exemption for Regenera Limited. Below is a table of all documents attached.

02/03/2005	Letter to Optionholder
28/02/2005	Half Yearly Report/Half Year Accounts
31/01/2005	Commitments Test Entity - Second Quarter Report
31/01/2005	Investor Update
27/01/2005	Response to ASX Query re: Article in AFR
27/01/2005	Response to ASX Query:Article in Australian Financial Review
11/01/2005	Change of Share Registry
11/01/2005	Newsletter to Shareholders - Company Update
14/12/2004	Appendix 3B - New Issue
06/12/2004	Change of Director's Interest Notice
23/11/2004	Results of Meeting
22/11/2004	Appendix 3B - Conversion of Performance Shares
16/11/2004	Update on RGA Offer to Retmed P/L Shareholders
29/10/2004	Commitments Test Entity - First Quarter Report
25/10/2004	Annual Report & Notice of AGM
21/10/2004	Offers to acquire remaining 100% of Retmed Pty Ltd
20/10/2004	Ethics Approval- Additional Phase III Visagen Clinical Trial
	<del></del>

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THOUSON

Yours sincerely

Stuart Usher

Joint CFO & Company Secretary



## RECEIVED.

OFFICE OF INTERNATIONAL CORPORATE FINANCE

2005 MAR -8 A 9: C8 - 3

20 October 2004

The Manager

Company Announcements

Australian Stock Exchange

4th Floor 20 Bridge Street

SYDNEY NSW 2000

Dear Sir

# Regenera Receives Ethics Approval for Additional Phase III Clinical Trial of Visagen™

Perth, Australia, Wednesday October 20, 2004: Regenera Limited (ASX: RGA) announced today that it had received human ethics approval for an additional clinical trial to be conducted in Singapore using intravitreal injections of its product Visagen™ (triamcinolone acetonide or "TA") in a preservative free form for treating Macular Oedema.

This approval permits the commencement of the second of the five clinical trials Regenera has planned in conjunction with the Singapore Eye Research Institute (SERI), an arm of the prestigious Singapore National Eye Center. The trials have been designated "Phase III" clinical trials by Singapore's regulating body, the Health Sciences Authority.

According to Dr William Ardrey, CEO of Regenera: "This validation by human ethics committee approval represents an important further step forward for Regenera's clinical development program."

"Approval to commence the second human clinical trial for Visagen™ demonstrates Regenera's capacity to deliver on its stated clinical development strategy and furthers our positive collaboration with SERI."

This second human clinical trial of Visagen™ at SERI targets Macular Oedema. Refractory or cystoid macular oedema often results from disease (associated with diabetic retinopathies, uveitis, retinitis pigmentosa and vein occlusions), injury, and occasionally following surgery (for example following uncomplicated cataract surgery). Leakage from local vessels into the layers of the macula results in swelling of the macula, presenting as blurred and distorted vision, sometimes with a pink tint and sensitivity to light. Permanent vision loss is rare, but recovery can be a gradual process. Current treatment is usually anti-inflammatory eye drops. For the Regenera

study, 20 patients will receive multiple intravitreal injections of Visagen™ and followed for an initial six month period, which may be extended to one year.

This complements the Uveitis trial which was the first of the clinical trials of Visagen™ to be commenced at SERI. Uveitis is an inflammation of the structures that make up the uveal tract, including the iris, ciliary body and choroid. Uveitis is the third leading cause of blindness in the U.S., causing 30,000 new cases of blindness a year and up to 10% of all cases of blindness.

The clinical development plan for Visagen™ also includes further human clinical trials at SERI in Age-Related Macular Degeneration; Diabetic Macular Oedema and also for use of Visagen™ by ophthalmologists as a visualisation device during the surgical procedure vitrectomy, or removal of the clear vitreous gel of the eye. Vitrectomy is the most common surgical procedure performed by retinal ophthalmology specialists.

## About Regenera:

Regenera operates in the area of ophthalmology and has developed treatments specifically for diseases of the back of the eye such as age-related macular degeneration (AMD) and diabetes-related (D-R) eye diseases.

The Company listed on the Australian Stock Exchange on 16 June, having raised more than AUD\$10 million in an Initial Public Offering which was oversubscribed by \$2 million.

Visagen™, Regenera's main product, is under development for the treatment of AMD and D-R eye diseases. Visagen is a preservative free formulation of the synthetic steroid, triamcinolone acetonide (TA), a proven treatment of AMD.

Recent clinical studies have demonstrated the effectiveness of TA in treating these diseases either alone or in conjunction with other treatments.

## For further information please contact:

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Dr William Ardrey

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CEO, Regenera Ltd

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The Manager
Company Announcements
Australian Stock Exchange
4th Floor 20 Bridge Street
SYDNEY NSW 2000

Dear Sir

# Regenera Offers to Acquire Remaining 100% of Retmed Pty Ltd Subject to Shareholder Approval

**Perth, Australia, Thursday October 21, 2004:** Regenera Limited (ASX: RGA) is pleased to announce its intention to acquire the minority shareholdings of its product development subsidiary, Retmed Pty Ltd ("Retmed") subject to shareholder approval at the Regenera Annual General Meeting on 23<sup>rd</sup> of November 2004.

The Chairman of Regenera, Mr Tony Fitzgerald commented "Completion of the acquisition of Retmed will simplify the corporate structure of Regenera and provide the opportunity for Regenera to fully capture the value of any transactions which may arise out of the commercialisation of the patented technologies owned by Retmed."

A Resolution will be put to the shareholders of Regenera at the AGM seeking approval for the Directors to allot and issue 22,420,000 Shares and 5,900,000 Options to the Retmed Shareholders in consideration for the acquisition of all of their Retmed Shares.

The acquisition of the Retmed Shares will be conditional on:

- (a) Regenera obtaining all necessary regulatory and Shareholder approvals required to issue the Shares and Options to the Retmed Shareholders; and
- (b) Regenera having received sufficient acceptances from the Retmed Shareholders to give it a relevant interest in at least 80% of the issued capital of Retmed; and
- (c) The Retmed shareholders entering into an escrow agreement, which would mean that the Retmed shareholders would not be able to sell the Regenera Shares arising out of the acquisition for a period of 12months.

Currently Regenera is entitled to 51% of the voting rights of Retmed. If Regenera acquires all of the Retmed Shares currently on issue, Retmed will become a wholly owned subsidiary of Regenera. This would entitle Regenera to 100% of any potential revenue streams arising from commercialisation of the Retmed intellectual property.

Dr William Ardrey, CEO of Regenera, said: "The acquisition of Retmed will complement the intellectual property Regenera has developed and acquired, all of which focus on providing tools for ophthalmologists to treat their patients with back of the eye disorders, the leading cause of vision loss in the western world."

## About Regenera:

Regenera operates in the area of ophthalmology and has developed treatments specifically for diseases of the back of the eye such as age-related macular degeneration (AMD) and diabetes-related (D-R) eye diseases.

The Company listed on the Australian Stock Exchange on 16 June, having raised more than AUD\$10 million in an Initial Public Offering which was oversubscribed by \$2 million.

Visagen™, Regenera's main product, is under development for the treatment of AMD and D-R eye diseases. Visagen is a preservative free formulation of the synthetic steroid, triamcinolone acetonide (TA), a proven treatment of AMD.

Recent clinical studies have demonstrated the effectiveness of TA in treating these diseases either alone or in conjunction with other treatments.

## **About Retmed Pty Ltd:**

Retmed is the product development project subsidiary company of Regenera and was established in 2001 by Dr Philip Penfold for the purpose of commercialising a platform of proprietary therapeutics for the treatment of inflammatory diseases of the eye. Retmed has patent rights assigned from The University of Sydney including for the use of the corticosteroid triamcinolone acetonide (TA) in treating the retinal disease, macular degeneration. Retmed is developing additional complementary intellectual property relating to the treatment of eye diseases.

On 1 July 2004 Regenera announced that it had completed the acquisition of a 51% interest in Retmed Pty Ltd and as contemplated in the Regenera Limited IPO prospectus dated 8th April 2004.

## For further information please contact:

Media:

Company:

Rebecca Christie

Stuart Usher

**Buchan Consulting Pty Ltd** 

Joint Company Secretary

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Regenera Ltd

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Rule 4.7B

OFFICE OF RITERMATICNESS

## **Appendix 4C**

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

Name of entity	
Regenera Limited	
ABN	Quarter ended ("current quarter")
35 107 371 460	30 September 2004

## Consolidated statement of cash flows

Cash flows related to operating activities		Current quarter \$A'000	Year to date \$A'000
1.1	Receipts from customers		
1.2	Payments for  (a) staff costs (b) advertising and marketing (c) research and development (d) leased assets (e) other working capital	(190) (42) (318) - (254)	(190) (42) (318) - (254)
1.3 1.4	Dividends received  Interest and other items of a similar nature received	80	65
1.5 1.6 1.7	Interest and other costs of finance paid Income taxes paid Other (provide details if material)		
1.7	(a) Consulting and professional services	(437)	(437)
	(b) Travel	(138)	(138)
	Net operating cash flows	(1,299)	(1,299)

<sup>+</sup> See chapter 19 for defined terms.

		Current quarter	Year to date
<del>-</del>		\$A'000	\$A'000
1.8	Net operating cash flows (carried forward)	(1,299)	(1,299)
1.9	Cash flows related to investing activities Payment for acquisition of:  (a) businesses (item 5)		
1 10	<ul> <li>(b) equity investments</li> <li>(c) intellectual property</li> <li>(d) physical non-current assets</li> <li>(e) other non-current assets</li> </ul>	(1,960) (131) (42)	(1,960) (131) (42)
1.10	Proceeds from disposal of:  (a) businesses (item 5)  (b) equity investments  (c) intellectual property  (d) physical non-current  assets  (e) other non-current assets		
1.11	Loans to other entities		
1.12	Loans repaid by other entities Other (provide details if material)  (a) Cash introduced on acquisition of controlled entity	112	112
	Net investing cash flows	(2,021)	(2,021)
1.14	Total operating and investing cash flows		
1.15 1.16 1.17 1.18 1.19	Cash flows related to financing activities Proceeds from issues of shares, options, etc. Proceeds from sale of forfeited shares Proceeds from borrowings Repayment of borrowings Dividends paid	19	19
1.20	Other (costs of capital raising)	(65)	(65)
	Net financing cash flows	(46)	(46)
	Net increase (decrease) in cash held	(3,366)	(3,366)
1.21 1.22	Cash at beginning of quarter/year to date Exchange rate adjustments to item 1.20	9,929	9,929
1.23	Cash at end of quarter	6,563	6,563

Appendix 4C Page 2 30/9/2001

<sup>+</sup> See chapter 19 for defined terms.

# Payments to directors of the entity and associates of the directors Payments to related entities of the entity and associates of the related entities

		SA'000
.24	Aggregate amount of payments to the parties included in item 1.2	165
.25	Aggregate amount of loans to the parties included in item 1.11	-
.26	Explanation necessary for an understanding of the transactions  Mr Tony Fitzgerald the Executive Chairman of Regenera Ltd is also Growth Partners which provided corporate advisory services and financi the company during the time of the transactions as follows:  \$95k - Corporate advisory  \$70k - Salaries of both Mr Fitzgerald and Dr Ardrey	
	n-cash financing and investing activities  Details of financing and investing transactions which have had a mater	rial effect on consolidated
	n-cash financing and investing activities  Details of financing and investing transactions which have had a mater assets and liabilities but did not involve cash flows	rial effect on consolidated
	n-cash financing and investing activities  Details of financing and investing transactions which have had a mater	rial effect on consolidated
.1	n-cash financing and investing activities  Details of financing and investing transactions which have had a mater assets and liabilities but did not involve cash flows	
<b>No</b> 1	n-cash financing and investing activities  Details of financing and investing transactions which have had a mater assets and liabilities but did not involve cash flows  N/A  Details of outlays made by other entities to establish or increase their sh	

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	_	-
3.2	Credit standby arrangements	-	-

30/9/2001

<sup>+</sup> See chapter 19 for defined terms.

### Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter \$A'000	Previous quarter \$A'000
4.1	Cash on hand and at bank	503	
4.2	Deposits at call	6,060	9,929
4.3	Bank overdraft		
4.4	Other (provide details)		
	Total: cash at end of quarter (item 1.22)	6,563	9,929

## Acquisitions and disposals of business entities

		Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1	Name of entity	N/A	N/A
5.2	Place of incorporation or registration		
5.3	Consideration for acquisition or disposal		
5.4	Total net assets		
5.5	Nature of business	4,300,000	

## Compliance statement

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Stuart Usher

Joint CFO & Company Secretary

29 September 2004

Appendix 4C Page 4 30/9/2001

<sup>+</sup> See chapter 19 for defined terms.

## **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
- 2. The definitions in, and provisions of, AASB 1026: Statement of Cash Flows apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 itemised disclosure relating to acquisitions
  - 9.4 itemised disclosure relating to disposals
  - 12.1(a) policy for classification of cash items
  - 12.3 disclosure of restrictions on use of cash
  - 13.1 comparative information
- 3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

30/9/2001 Appendix 4C Page 5

<sup>+</sup> See chapter 19 for defined terms.



The Manager Company Announcements Australian Stock Exchange 4th Floor 20 Bridge Street SYDNEY NSW 2000

Dear Sir

# Update on Regenera Limited Offer to Retmed Pty Ltd Shareholders Subject to Shareholder Approval

**Perth, Australia, Tuesday 16 November, 2004:** Regenera Limited (ASX: RGA) is pleased to announce that its Share and Option offer to the minority shareholders of Retmed Pty Ltd ("Retmed") has been unanimously accepted by the Retmed shareholders. Retmed is currently the 51% controlled product development subsidiary of Regenera.

Completion of the 100% acquisition of Retmed is now subject to shareholder approval at the Regenera Annual General Meeting on 23<sup>rd</sup> of November 2004.

The Chairman of Regenera, Mr Tony Fitzgerald said "The board of Regenera is very pleased with the rapid and unanimous acceptance by all Retmed shareholders of the offer. Completion of the acquisition will simplify the corporate structure of Regenera and provide the opportunity for Regenera to fully capture the value of any transactions which may arise out of the commercialisation of the patented technologies owned by Retmed."

A Resolution will be put to the shareholders of Regenera at the AGM seeking approval for the Directors to allot and issue 22,420,000 Shares and 5,900,000 Options to the Retmed Shareholders in consideration for the acquisition of all of their Retmed Shares.

Dr William Ardrey, CEO of Regenera, said: "The acquisition of Retmed will complement the intellectual property Regenera has developed and acquired, all of which focus on providing tools for ophthalmologists to treat their patients with back of the eye disorders, the leading cause of vision loss in the western world. Following shareholder approval, Regenera will be entitled to 100% of all potential revenue streams arising from commercialisation of the Retmed intellectual property." Dr Ardrey added, "We are confident that the Share and Option consideration paid for the balance of Retmed will be value accretive to all Regenera shareholders. We similarly remain confident of generating licence income in the near term from our IP portfolio."

## About Regenera:

Regenera operates in the area of ophthalmology and has developed treatments specifically for diseases of the back of the eye such as age-related macular degeneration (AMD) and diabetes-related (D-R) eye diseases.

The Company listed on the Australian Stock Exchange on 16 June, having raised more than AUD\$10 million in an Initial Public Offering which was oversubscribed by \$2 million.

Visagen™, Regenera's main product, is under development for the treatment of AMD and D-R eye diseases. Visagen is a preservative free formulation of the synthetic steroid, triamcinolone acetonide (TA), a proven treatment for AMD.

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On 1 July 2004 Regenera announced that it had completed the acquisition of a 51% interest in Retmed Pty Ltd as contemplated in the Regenera Limited IPO prospectus dated 8th April 2004

## For further information please contact:

Media:

Company:

Rebecca Christie

Dr. William J. Ardrey

**Buchan Consulting Pty Ltd** 

**Chief Executive Officer** 

SYDNEY:

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## RECEIVEL



22 November 2004

The Manager Company Announcements Australian Stock Exchange 4<sup>th</sup> Floor 20 Bridge Street SYDNEY NSW 2000

Dear Sir

## Appendix 3B - Conversion of Performance Shares

We attach Appendix 3B covering the issue of 10,000,000 ordinary shares resulting from the satisfaction of the performance milestone relating to the Class C Performance Shares.

The ordinary shares relating to the conversion of the Performance shares are still subject to escrow conditions imposed by the ASX. Accordingly, we are not seeking the listing of these shares for trading at this time.

The Company is pleased to advise that it has received a favorable ruling by the U.S. Food and Drug Administration (FDA) relating to the designation of the use of Triamcinolone Acetonide (TA) as a device rather than a drug in the area of visualization for Vitrectomy surgery. The FDA has indicated that the effectiveness of TA is supported by the clinical information already submitted to them. Our US regulatory advisers confirm that this means no further clinical studies will be necessary to document safety and effectiveness of the product and thus to gain FDA approval for clinical use of the product in the US. This satisfies the Class C performance milestone to prepare TA for US FDA registration, without the need for further clinical trials.

The Company is pleased to have achieved such a positive outcome for the first application of TA for use in the eye.

Yours sincerely

Stuart Usher

Joint Company Secretary

Rule 2.7, 3.10.3, 3.10.4, 3.10.5

## Appendix 3B

# New issue announcement, application for quotation of additional securities and agreement

Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.

Introduced 1/7/96. Origin: Appendix 5. Amended 1/7/98, 1/9/99, 1/7/2000, 30/9/2001, 11/3/2002, 1/1/2003.

Name	of entity	
	Regenera Limited	
ABN		
35	107 371 460	
We (	the entity) give ASX the following i	information.
	t 1 - All issues  sust complete the relevant sections (attach s	heets if there is not enough space).
1	<sup>+</sup> Class of <sup>+</sup> securities issued or to be issued	Ordinary Fully Paid Restricted (RGAAY)
2	Number of *securities issued or to be issued (if known) or maximum number which may be issued	10,000,000 Ordinary Fully Paid Restricted
3	Principal terms of the *securities (eg, if options, exercise price and expiry date; if partly paid *securities, the amount outstanding and due dates for payment; if *convertible securities, the conversion price and dates for conversion)	Ordinary Fully Paid Shares

1/1/2003 Appendix 3B Page 1

<sup>+</sup> See chapter 19 for defined terms.

4	Do the *securities rank equally in all respects from the date of allotment with an existing *class of quoted *securities?	Yes	
	If the additional securities do not rank equally, please state:  • the date from which they do  • the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment  • the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment		
5	Issue price or consideration	NIL	
6	Purpose of the issue (If issued as consideration for the acquisition of assets, clearly identify those assets)	(RGAAC 8,290,000 and	e Third Milestone. All
7	Dates of entering *securities into uncertificated holdings or despatch of certificates	22 November 2004	
		Number	+Class
8	Number and +class of all	25,059,094	Ordinary Shares
	*securities quoted on ASX (including the securities in clause 2 if applicable)	20,224,814	Options
			l

Appendix 3B Page 2 1/1/2003

<sup>+</sup> See chapter 19 for defined terms.

9 Number and \*class of all \*securities not quoted on ASX (including the securities in clause 2 if applicable)

	Number	+Class
.	25,190,572	Ordinary shares
	21,476,432	Options expiring 30 June 2007 exercisable at \$0.60
	5,000,000	Class A Performance shares
	5,000,000	Class B Performance shares
	10,000,000	Class D Performance shares
	15,000,000	Class E Performance shares
	20,000,000	Class F Performance shares

Dividend policy (in the case of a trust, distribution policy) on the increased capital (interests)

Not applicable	

## Part 2 - Bonus issue or pro rata issue

11	Is security holder approval required?	
12	Is the issue renounceable or non-renounceable?	
	•	
		PRODUCTION TO THE PRODUCTION OF THE PRODUCTION O
13	Ratio in which the *securities will be offered	
14	<sup>+</sup> Class of <sup>+</sup> securities to which the offer relates	
	•	· · · · · · · · · · · · · · · · · · ·
	•	
15	<sup>+</sup> Record date to determine entitlements	
	•	
1.0	W/11 1 - 1 1/2 1/20 1 - 4 1	
16	Will holdings on different registers (or subregisters) be aggregated for calculating entitlements?	

1/1/2003

<sup>+</sup> See chapter 19 for defined terms.

Names of countries in which the entity has *security holders who will not be sent new issue documents  Note: Security holders must be told how their entitlements are to be dealt with.  Cross reference: rule 7.7.  Closing date for receipt of acceptances or renunciations  Names of any underwriters  Amount of any underwriting fee or commission  Names of any brokers to the issue  Fee or commission payable to the broker to the issue  Amount of any handling fee payable to brokers who lodge acceptances or renunciations on behalf of *security holders  If the issue is contingent on	
entitlements are to be dealt with.  Cross reference: rule 7.7.  19 Closing date for receipt of acceptances or renunciations 20 Names of any underwriters  21 Amount of any underwriting fee or commission  22 Names of any brokers to the issue  23 Fee or commission payable to the broker to the issue  24 Amount of any handling fee payable to brokers who lodge acceptances or renunciations on behalf of *security holders	
acceptances or renunciations  Names of any underwriters  Amount of any underwriting fee or commission  Names of any brokers to the issue  Fee or commission payable to the broker to the issue  Amount of any handling fee payable to brokers who lodge acceptances or renunciations on behalf of *security holders	
20 Names of any underwriters  21 Amount of any underwriting fee or commission  22 Names of any brokers to the issue  23 Fee or commission payable to the broker to the issue  24 Amount of any handling fee payable to brokers who lodge acceptances or renunciations on behalf of *security holders	
22 Names of any brokers to the issue  23 Fee or commission payable to the broker to the issue  24 Amount of any handling fee payable to brokers who lodge acceptances or renunciations on behalf of *security holders	
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payable to brokers who lodge acceptances or renunciations on behalf of *security holders	
25 If the issue is contingent on	
*security holders' approval, the date of the meeting	
26 Date entitlement and acceptance form and prospectus or Product Disclosure Statement will be sent to persons entitled	
27 If the entity has issued options, and the terms entitle option holders to participate on exercise, the date on which notices will be sent to option holders	
Date rights trading will begin (if applicable)	
29 Date rights trading will end (if applicable)	

Appendix 3B Page 4 1/1/2003

<sup>+</sup> See chapter 19 for defined terms.

	[	
30	How do *security holders sell their entitlements in full through a broker?	
31	How do *security holders sell <i>part</i> of their entitlements through a broker and accept for the balance?	
32	How do *security holders dispose of their entitlements (except by sale through a broker)?	
33	<sup>+</sup> Despatch date	
	t 3 - Quotation of securi	
34	Type of securities (tick one)	
(a)	Securities described in Part 1	
(b)		f the escrowed period, partly paid securities that become fully paid, employee nds, securities issued on expiry or conversion of convertible securities
Enti	ties that have ticked box 34(a	)
Addi	tional securities forming a new clas	ss of securities
Tick to docum	o indicate you are providing the informati ents	on or
35		securities, the names of the 20 largest holders of the number and percentage of additional *securities held by
36	If the *securities are *equity *securities setting out the numb 1 - 1,000 1,001 - 5,000 5,001 - 10,000 10,001 - 100,000 100,001 and over	securities, a distribution schedule of the additional per of holders in the categories
37	A copy of any trust deed for th	e additional <sup>+</sup> securities
+ See o	chapter 19 for defined terms.	

1/1/2003

Entit	Entities that have ticked box 34(b)				
38	Number of securities for which <sup>+</sup> quotation is sought				
39	Class of *securities for which quotation is sought				
40	Do the *securities rank equally in all respects from the date of allotment with an existing *class of quoted *securities?				
	If the additional securities do not rank equally, please state:  the date from which they do  the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment  the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment				
41	Reason for request for quotation now  Example: In the case of restricted securities, end of restriction period				
	(if issued upon conversion of another security, clearly identify that other security)				
42	Number and *class of all *securities quoted on ASX (including the securities in clause 38)	Number	<sup>+</sup> Class		

Appendix 3B Page 6 1/1/2003

<sup>+</sup> See chapter 19 for defined terms.

### Quotation agreement

- <sup>†</sup>Quotation of our additional <sup>†</sup>securities is in ASX's absolute discretion. ASX may quote the <sup>†</sup>securities on any conditions it decides.
- We warrant the following to ASX.
  - The issue of the \*securities to be quoted complies with the law and is not for an illegal purpose.
  - There is no reason why those \*securities should not be granted \*quotation.
  - An offer of the \*securities for sale within 12 months after their issue will not require disclosure under section 707(3) or section 1012C(6) of the Corporations Act.

Note: An entity may need to obtain appropriate warranties from subscribers for the securities in order to be able to give this warranty

- Section 724 or section 1016E of the Corporations Act does not apply to any applications received by us in relation to any \*securities to be quoted and that no-one has any right to return any \*securities to be quoted under sections 737, 738 or 1016F of the Corporations Act at the time that we request that the \*securities be quoted.
- We warrant that if confirmation is required under section 1017F of the Corporations Act in relation to the \*securities to be quoted, it has been provided at the time that we request that the \*securities be quoted.
- If we are a trust, we warrant that no person has the right to return the \*securities to be quoted under section 1019B of the Corporations Act at the time that we request that the \*securities be quoted.

1/1/2003 Appendix 3B Page 7

<sup>+</sup> See chapter 19 for defined terms.

- We will indemnify ASX to the fullest extent permitted by law in respect of any claim, action or expense arising from or connected with any breach of the warranties in this agreement.
- We give ASX the information and documents required by this form. If any information or document not available now, will give it to ASX before \*quotation of the \*securities begins. We acknowledge that ASX is relying on the information and documents. We warrant that they are (will be) true and complete.

Stuart Usher

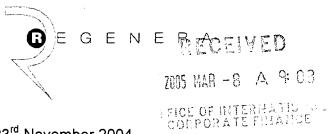
Joint Company Secretary

LIL

22 November 2004

Appendix 3B Page 8 1/1/2003

<sup>+</sup> See chapter 19 for defined terms.



23<sup>rd</sup> November 2004

The Manager Company Announcements Australian Stock Exchange 4<sup>th</sup> Floor 20 Bridge Street SYDNEY NSW 2000

Dear Sir

## RESULTS OF ANNUAL GENERAL MEETING

In accordance with Listing Rule 3.13.2 and Section 251AA of the Corporations Act, the following information is provided in relation to resolutions passed by shareholders of Regenera Ltd at the Annual General Meeting held at 12.00pm Tuesday, 23 November 2004.

	1	2	3	4
	Ord	Ord	Ord	Ord
Resolution Number	See annexure	See annexure	See annexure	See annexure
	1	1	1	2
Decided by a show of	Yes	Yes	Yes	Yes
hands				
Call for a poll	No	No	No	No
Total number of proxy	13,066,470	13,066,470	13,066,470	13,066,470
votes exercisable by				
proxies validly appointed				
Details of proxy votes in				
respect of which the proxy				
specified that:		· · ·	:	
The proxy vote in favour	13,051,220	13,051,220	13,051,220	13,028,220
of the Resolution				
The proxy vote against the	-	-	-	-
Resolution				
The proxy abstain from	-	-	-	23,000
voting on the Resolution				
The proxy may vote at the	15,250	15,250	15,250	15,250
proxy's discretion				
Total votes cast on a poll	N/A	N/A	N/A	N/A
in favour of the resolution		7.4		
Total votes cast on a poll	N/A	N/A	N/A	N/A
against the resolution	——————————————————————————————————————			
Total votes cast on a poll	N/A	N/A	N/A	N/A
abstaining on the				
resolution				

Total votes exercisable by proxies which were not cast	N/A	N/A	N/A	N/A
Outcome of Resolution	Approved	Approved	Approved	Approved

For and on behalf of the Board of Directors:

Stuart Usher

Joint Company Secretary

LUL.

#### Annexure 1

## Resolution 1 - Re-election of Mr. Finian MacCana

To consider and, if thought fit, to pass, with or without amendment, the following resolution as an **ordinary resolution**:

"That, Mr Finian MacCana who retires by rotation in accordance with clause 13.2 of the Company's Constitution and, being eligible, be reelected as a Director."

## Resolution 2 – Re-election of Mr. Stephen Newman

To consider and, if thought fit, to pass, with or without amendment, the following resolution as an **ordinary resolution**:

"That, Mr. Stephen Newman who retires by rotation in accordance with clause 13.2 of the Company's Constitution and, being eligible, be reelected as a Director."

## Resolution 3 – Re-election of Mr. Anthony Fitzgerald

To consider and, if thought fit, to pass, with or without amendment, the following resolution as an **ordinary resolution**:

"That, Mr. Anthony Fitzgerald who retires by rotation in accordance with clause 13.2 of the Company's Constitution and, being eligible, be re-elected as a Director."

## Annexure 2

## Resolution 4 - Acquisition of Retmed Shares

To consider and, if thought fit, to pass, with or without amendment, the following resolution as an **ordinary resolution**:

"That, for the purposes of Listing Rule 7.1 of the ASX Listing Rules and for all other purposes, approval is given for the Directors to allot and issue up to 22,420,000 Shares and 5,900,000 Options to the Retmed Shareholders in consideration for the acquisition of their shares in Retmed Pty Ltd on the terms and conditions in the Explanatory Memorandum."

RECEIVED

2005 MAR -8 A 9:07

Rule 2.7, 3.10.3, 3.10.4, 3.10.5

# OFFICE OF INTERMIT

## **Appendix 3B**

# New issue announcement, application for quotation of additional securities and agreement

Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.

Introduced 1/7/96. Origin: Appendix 5. Amended 1/7/98, 1/9/99, 1/7/2000, 30/9/2001, 11/3/2002, 1/1/2003.

Regenera Limited

ABN

35 107 371 460

We (the entity) give ASX the following information.

## Part 1 - All issues

You must complete the relevant sections (attach sheets if there is not enough space).

1 \*Class of \*securities issued or to be issued

Ordinary Fully Paid Shares - Restricted Options - Restricted

Number of \*securities issued or to be issued (if known) or maximum number which may be issued

22,420,000 Ordinary Fully Paid Shares – Restricted to 16 June 2004
5,900,000 Options – Restricted to 16 June 2005

3 Principal terms of the \*securities (eg, if options, exercise price and expiry date; if partly paid \*securities, the amount outstanding and due dates for payment; if \*convertible securities, the conversion price and dates for conversion)

If exercised prior to 30 April 2005, the exercise price will be 75 cents per share.

If exercised between 1 May 2005 and 30 June 2008 (Expiry Date), the exercise price will be \$1.10 per share.

<sup>+</sup> See chapter 19 for defined terms.

Do the \*securities rank equally in all respects from the date of allotment with an existing \*class of quoted \*securities?

If the additional securities do not rank equally, please state:

- the date from which they do
- the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment
- the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment

Ordinary Shares – Yes Options – Only on exercise

5 Issue price or consideration

\$10,500,000

6 Purpose of the issue
(If issued as consideration for the acquisition of assets, clearly identify those assets)

Acquisition of all the Retmed Pty Ltd Shares which the Company currently does not own which was approved by shareholders at AGM held 23 November 2004.

- 7 Dates of entering \*securities into uncertificated holdings or despatch of certificates
- 8 December 2004
- 8 Number and \*class of all \*securities quoted on ASX (including the securities in clause 2 if applicable)

Number	+Class
25,059,094	Ordinary Shares
20,224,814	Options

Appendix 3B Page 2

<sup>+</sup> See chapter 19 for defined terms.

9 Number and \*class of all \*securities not quoted on ASX (including the securities in clause 2 if applicable)

Number	+Class
47,610,572	Ordinary shares
21,476,432	Options expiring 30 June 2007 exercisable at \$0.60
5,900,000	Options expiring 30 June 2008 exercisable at 75cents
5,000,000	Class A Performance shares
5,000,000	Class B Performance shares
10,000,000	Class D Performance shares
15,000,000	Class E Performance shares
20,000,000	Class F Performance shares

Dividend policy (in the case of a trust, distribution policy) on the increased capital (interests)

Not applicable		

## Part 2 - Bonus issue or pro rata issue

11	Is security holder approval required?
12	Is the issue renounceable or non-renounceable?
13	Ratio in which the *securities will be offered
14	<sup>+</sup> Class of <sup>+</sup> securities to which the offer relates
15	<sup>+</sup> Record date to determine entitlements

<sup>+</sup> See chapter 19 for defined terms.

16	Will holdings on different registers (or subregisters) be aggregated for	İ
	calculating entitlements?	
	•	
17	Policy for deciding entitlements in	
	relation to fractions	
18	Names of countries in which the	
	entity has *security holders who	
	will not be sent new issue documents	
	Note: Security holders must be told how their entitlements are to be dealt with.	
	Cross reference: rule 7.7.	
10		
19	Closing date for receipt of acceptances or renunciations	
20	Names of any underwriters	
20	rames of any underwriters	
21	Amount of any underwriting fee or commission	
	Commission	
22	Names of any brokers to the issue	
23	Fee or commission payable to the	
	broker to the issue	
24	Amount of any handling fee payable to brokers who lodge	
	acceptances or renunciations on	
	behalf of *security holders	
25	If the issue is contingent on +security holders' approval, the	
	date of the meeting	
26	Date entitlement and acceptance	
	form and prospectus or Product Disclosure Statement will be sent to	
	persons entitled	
	•	
27	If the entity has issued options, and	
	the terms entitle option holders to participate on exercise, the date on	
	which notices will be sent to option	
	holders	
28	Date rights trading will begin (if	

Appendix 3B Page 4

<sup>+</sup> See chapter 19 for defined terms.

	applicable)		
29	9 Date rights trading will end (if applicable)		
30	O How do *security holders sell their entitlements in full through a broker?		
31	1 How do *security holders sell part of their entitlements through a broker and accept for the balance?		
32	2 How do *security holders dispose of their entitlements (except by sale through a broker)?		
33	3 *Despatch date		
	art 3 - Quotation of securities u need only complete this section if you are applying for quotation of securities  Type of securities (tick one)		
(a)	a) $$ Securities described in Part 1	Securities described in Part 1	
(b)	b) All other securities		
	Example: restricted securities at the end of the escrowed period, partly paid securities that become fully paid, employee incentive share securities when restriction ends, securities issued on expiry or conversion of convertible securities		
Entit	ntities that have ticked box 34(a)		
Addit	ditional securities forming a new class of securities		
	ck to indicate you are providing the information or cuments		
35	If the *securities are *equity securities, the names of the 20 largest holders of the additional *securities, and the number and percentage of additional *securities held by those holders		
36	If the *securities are *equity securities, a distribution schedule of the additiona *securities setting out the number of holders in the categories 1 - 1,000		
+ See c	See chapter 19 for defined terms.		

1/1/2003

	1,001 - 5,000 5,001 - 10,000 10,001 - 100,000 100,001 and over		
37	A copy of any trust deed for the	e additional <sup>+</sup> securities	
Entit	ies that have ticked box 34(b	)	
38	Number of securities for which †quotation is sought		
39	Class of *securities for which quotation is sought		
40	Do the *securities rank equally in all respects from the date of allotment with an existing *class of quoted *securities?		
	If the additional securities do not rank equally, please state:  the date from which they do  the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment  the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment		
41	Reason for request for quotation now  Example: In the case of restricted securities, end of restriction period		
	(if issued upon conversion of another security, clearly identify that other security)		
42	Number and *class of all *securities quoted on ASX (including the securities in clause 38)	Number	<sup>+</sup> Class

Appendix 3B Page 6 1/1/2003

<sup>+</sup> See chapter 19 for defined terms.

### Quotation agreement

- <sup>†</sup>Quotation of our additional \*securities is in ASX's absolute discretion. ASX may quote the \*securities on any conditions it decides.
- We warrant the following to ASX.
  - The issue of the \*securities to be quoted complies with the law and is not for an illegal purpose.
  - There is no reason why those \*securities should not be granted \*quotation.
  - An offer of the \*securities for sale within 12 months after their issue will not require disclosure under section 707(3) or section 1012C(6) of the Corporations Act.

Note: An entity may need to obtain appropriate warranties from subscribers for the securities in order to be able to give this warranty

- Section 724 or section 1016E of the Corporations Act does not apply to any applications received by us in relation to any \*securities to be quoted and that no-one has any right to return any \*securities to be quoted under sections 737, 738 or 1016F of the Corporations Act at the time that we request that the \*securities be quoted.
- We warrant that if confirmation is required under section 1017F of the Corporations Act in relation to the \*securities to be quoted, it has been provided at the time that we request that the \*securities be quoted.
- If we are a trust, we warrant that no person has the right to return the \*securities to be quoted under section 1019B of the Corporations Act at the time that we request that the \*securities be quoted.

1/1/2003

<sup>+</sup> See chapter 19 for defined terms.

- We will indemnify ASX to the fullest extent permitted by law in respect of any claim, action or expense arising from or connected with any breach of the warranties in this agreement.
- We give ASX the information and documents required by this form. If any information or document not available now, will give it to ASX before \*quotation of the \*securities begins. We acknowledge that ASX is relying on the information and documents. We warrant that they are (will be) true and complete.

Stuart Usher

Joint Company Secretary

the (D)

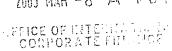
14 December 2004

Appendix 3B Page 8 1/1/2003

<sup>+</sup> See chapter 19 for defined terms.

2005 MAR -8 A 9: C9

Rule 3.19A.2



## Appendix 3Y

## **Change of Director's Interest Notice**

Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.

Introduced 30/9/2001.

Name of entity	Regenera Limited		
ABN	35 107 371 460		

We (the entity) give ASX the following information under listing rule 3.19A.2 and as agent for the director for the purposes of section 205G of the Corporations Act.

Name of Director	Finian Brendan MacCana
Date of last notice	6 October 2004

#### Part 1 - Change of director's relevant interests in securities

In the case of a trust, this includes interests in the trust made available by the responsible entity of the trust

Note: In the case of a company, interests which come within paragraph (i) of the definition of "notifiable interest of a director" should be disclosed in this part.

Direct or indirect interest	Direct
Nature of indirect interest (including registered holder) Note: Provide details of the circumstances giving rise to the relevant interest.	
Date of change	29 November 2004
No. of securities held prior to change	250,000 Options exercised at 60c expiring 30/06/07  The above securities are held in the name of Mr MacCana  190,000 Ordinary Shares 170,000 Options exercised at 60c expiring 30/06/07  90,000 Options exercised at 75c expiring 30/06/08
	The above securities are held by Lambert Mayfield Pty Ltd <the fund="" lambert="" super=""> of which Mr MacCana has a beneficial interest.</the>

<sup>+</sup> See chapter 19 for defined terms.

Class	Options
Number acquired	49,833
Number disposed	-
Value/Consideration Note: If consideration is non-cash, provide details and estimated valuation	\$3,316
No. of securities held after change	250,000 Options exercised at 60c expiring 30/06/07
	The above securities are held in the name of Mr MacCana
	190,000 Ordinary Shares 170,000 Options exercised at 60c expiring 30/06/07 139,833 Options exercised at 75c expiring 30/06/08
	The above securities are held by Lambert Mayfield Pty Ltd <the fund="" lambert="" super=""> of which Mr MacCana has a beneficial interest.</the>
Nature of change Example: on-market trade, off-market trade, exercise of options, issue of securities under dividend reinvestment plan, participation in buy-back	On-market Trade

## Part 2 – Change of director's interests in contracts

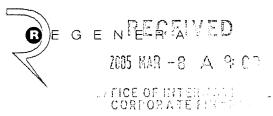
Note: In the case of a company, interests which come within paragraph (ii) of the definition of "notifiable interest of a director" should be disclosed in this part.

Detail of contract	N/A
Nature of interest	N/A
Name of registered holder (if issued securities)	N/A
Date of change	N/A
No. and class of securities to which interest related prior to change  Note: Details are only required for a contract in relation to which the interest has changed	N/A
Interest acquired	N/A
Interest disposed	N/A
Value/Consideration Note: If consideration is non-cash, provide details and an estimated valuation	N/A
Interest after change	N/A

11/3/2002

Appendix 3Y Page 2

<sup>+</sup> See chapter 19 for defined terms.



11<sup>th</sup> January 2005

The Manager Company Announcements Australian Stock Exchange 4<sup>th</sup> Floor 20 Bridge Street SYDNEY NSW 2000

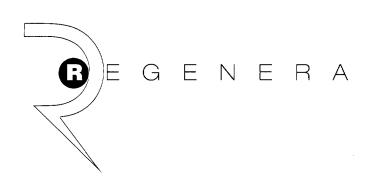
Dear Sir

## **COMPANY UPDATE - NEWSLETTER**

Please find attached a shareholder newsletter for Regenera Limited which will be distributed to shareholders.

Yours sincerely,

Dr. William J Ardrey IV Chief Executive Officer





Regenera Limited Newsletter   Issue 2   January 2005

Regenera Limited



# Message from the CEO

Let me open the New Year by thanking our current investors for their ongoing support, and welcoming new shareholders and stakeholders to the company. We were fortunate to commence the year with both our shares and options (ASX: RGA and ASX: RGAO) trading above initial offer price, and we will shortly announce a program in the USA to attract new investors to the company's share program in America (termed American Depository Receipts). In 2004, we got the company off to a solid start, and we are currently planning for success in 2005.

The company's initiatives for the current year revolve around three key milestones. The first involves commercial licensing for the company's products, principally in the application of corticosteroids for the treatment of vitreous and retinal diseases. One of the key products

where the company holds intellectual property positions involves the increased use of Triamcinolone Acetonide as an aide in vitreous surgery. Concluding a revenuegenerating commercial licensing transaction, and also offering a clear regulatory path to registration for this product, represent important deliverables to the company. Use of this product in vitreous surgery represents an increasingly important area of acceptance for patients, surgeons, and commercial licensing partners.

A second area involves advancing the development of the company's drug products, for the treatment of both neovascularisation and oedematous conditions in the back-of-eye market, a US\$3 billion segment in the growing US\$7 billion global market for ocular drugs. Details contained within this newsletter describe some of the specific target diseases, and we have

also provided some information on the well-known researchers and surgeons helping the company as scientific advisors. The third area of focus will be in cementing our existing research ties with several leading ophthalmic research institutes with the goal of accelerating the development of our product portfolio on a cost effective basis.

Many thanks again. As CEO, my focus remains on driving value creation for our shareholders, combined with ensuring high performance from our well experienced scientific and managerial team.

Regards,

WMBB

**Dr William Ardrey**CEO

# -2004, we got the company off to a solid start, and

# eare currently planning for success in 2005."

# New Disease Targets for Regenera's Products

## Diabetic Macular Oedema

One of the pathologies associated with the ocular implications of diabetes is diabetic macular oedema. This occurs when there is leakage and accumulation of fluid from the blood vessels within the macula, the central part of the retina, responsible for sharp vision. The first visual symptom is blurring of the middle, or just off the side, of central vision, which can progress to the point where focusing becomes difficult. Ten percent of diabetics will develop secondary macular oedema, although the risk and severity is related to the degree of diabetic retinopathy.

There are two types of diabetic macular oedema; focal, where the

leakage occurs from microaneurysms, and diffuse oedema, caused by dilated retinal capillaries. The current treatment modality for diabetic macular oedema is laser treatment, which is only effective for a certain number of cases. Focal laser treatment is used to close the microaneurysms in focal macular oedema, whereas grid laser treatment is used to close the leaking vessels in diffuse macular oedema. Since these vessels are supplying nutrients to the retinal cells, closing these vessels starves the 'downstream' cells, which can lead to death of these cells, which can also lead to reduced vision. The aim of laser treatment is to sustain the status of visual acuity.

Current ophthalmic literature shows that triamcinolone acetonide (the active ingredient in Visagen™) acts to reduce the exudation of fluids from the vessels in the retina by reducing the effects of inflammatory mediators, without the need of lasers, and improves visual acuity after treatment. Other products in Regenera's pipeline are intended to treat exudation without the associated rise in intraocular pressure sometimes observed with corticosteroids.

# Uveitis

Uveitis is the inflammation of structures of the uveal tract; the iris, the choroid, and the ciliary body. These structures lie between the tougher outer layer, the sclera, and

the retina. It can be caused by a number of factors, including virus or fungus, parasite, autoimmune disease, or ocular trauma. Frequently no cause for the disease is found. The disease itself is not entirely treatable, but can be controlled. The mainstay of treatment includes topical and oral treatments, mostly corticosteroids, with Visagen™ acting as the principal intravitreal corticosteroid to treat the site of inflammation. There is increased interest in the medical literature using triamcinolone acetonide (the active ingredient in Visagen™) to treat macular oedema secondary to uveitis, and Regenera is funding a Singapore-based clinical trial to determine the safety and efficacy of this mode of treatment.

# Regenera Awarded the Western Australian Science & Innovation Grant

Regenera, in collaboration with the Western Australian Biotechnology Research Institute, was awarded the highly competitive Science and Innovation award. This award, an initiative of the Western Australian Government Office of Science and Innovation, is aimed at fostering collaborations between Academia and Industry to engage in innovative and cutting edge research and

potential commercialisation of the technology.

The awardee is Ms Xuan Thi Le of the Nanochemistry Research Institute, at Curtin University of Technology, who will be working in collaboration with Regenera, on the synthesis, characterisation and optimisation of nanopolymeric particles in the treatment of

inflammatory related eye diseases.

Development of better drug delivery systems for back of the eye diseases remains a significant initiative for future Drug Development.

Nanotechnology is revolutionising the Healthcare, Medical, Electronics and Communications industries. In particular, nanoparticle delivery, via biodegradable polymeric nanoparticles, demonstrates

potential in controlling the release and targeting of drugs within the eye. Regenera is also pursuing other sustained release technologies and drug delivery systems. If successful, these novel technologies could provide major therapeutic advantages over currently available ocular treatments in the market.

# Advances in the Drug Development Program at Regenera

Since expanding Regenera's Intellectual Property/Product portfolio, significant progress has been made in the development of these pipeline products in the last quarter. We have established collaborative research programs with Centres of Research Excellence such as the Victorian College of Pharmacy, Monash University, Center for Clinical Research in the U.S., the Singapore Eve Research Institute and the

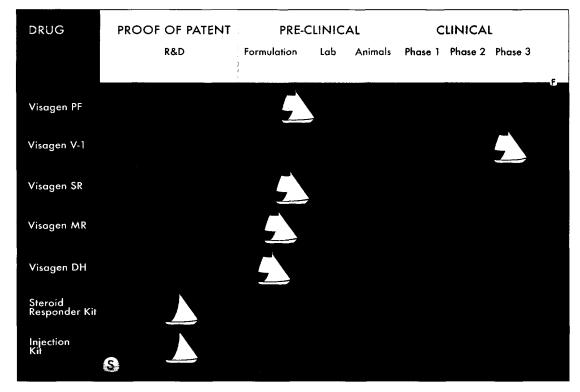
Western Australian Biotechnology
Research Institute. We have
successfully completed our first
major milestone in the Research and
Development Phase, namely the
proof of patent studies for Visagen
SR, Visagen MR and Visagen DH.
This progress has enhanced the
company's position for potential early
licensing negotiations. Pre-Clinical
studies will shortly be commenced at
the Singapore Eye Research Institute,

Monash University, Tulane University and potentially with The University of Western Australia.

We have recruited a core team of internationally renowned scientists to our Scientific Advisory Board with expertise in such diverse areas as Regulatory Affairs, Ophthalmology, Drug Development and Clinical Trials. Their vision and guidance have been instrumental in our progress to date.

Regenera has sponsored the attendance of several eminent scientists and surgeons to key scientific and medical conferences in the ocular field, such as ARVO and SERI-ARVO. So far, Regenera and its advisors have contributed sixteen scientific papers for presentation at these conferences, raising the profile of the company in both the scientific and medical communities.

# "We have recruited a core **team** of internationally **renowned scientists** to our Scientific Advisory Board"



A strong feature of Regenera is the knowledge and experience of the advisory team. Following are some of the current advisors to Regenera, ensuring quality products and sound practice. Our advisors are gathered from all fields, including regulatory clinical, commercial and scientific.

Gholam Peyman, MD: Dr Peyman has over 88 U.S. patents and 825 publications. in fields ranging from refractive surgery, intraocular lenses, intraocular tumours to drug delivery and vitreoretinal surgical techniques. He is also the author of nine textbooks. His fields of study stretch to the entire eve, and he is a pioneer in the area of intravitreal drug delivery and toxicity of many agents used in the eye for different indications. He is currently a Professor of Ophthalmology and Co-Director of the Vitreo-Retinal Service at Tulane University in New Orleans. Dr Peyman, along with creating and providing valuable intellectual property, designs and performs in vivo studies to determine efficacy and toxicity. His practical background, combined with his vast ophthalmic knowledge, sets a strong basis for Regenera's product development.

**Don Sanders, MD, PhD:** Dr Sanders has a PhD in Pharmacology and a Medical

degree, both from the University of Illinois, with extensive Regulatory (FDA) experience. He is a professional member of the American Academy of Ophthalmology, the American Society of Cataract and Refractive Surgery and the International Society of Refractive Surgery. He is well published, with over 130 journal articles and several editorships. Dr Sanders is currently an Associate Professor in the Department of Ophthalmology at the University of Illinois. Dr Sanders contributes and advises Regenera on Regulatory related matters. He is a driving force for all FDA and TGA submissions.

David S. Boyer, MD: Dr Boyer is one of Southern California's most prominent vitreoretinal specialists with over 25 years of experience. He is a Board-certified Ophthalmologist and a Senior Partner at the Retina-Vitreous Associates Medical Group in Beverly Hills and Torrance, CA. Dr Boyer is also a Clinical Associate Professor with the University of Southern California. A widely published author and avid lecturer, he has been commended with the awards of the American Academy of Ophthalmology Board of Trustees Honour Award Certificate, the 1996 Jules Stein Living Tribute Award, and the Retinitis Pigmentosa International Vision Award. Dr

Boyer's vast experience and knowledge provide Regenera with valuable tools and advice through all aspects of product development.

Dana Deupree, MD, FACS: Dr Deupree is a Board-certified Ophthalmologist, specialising in diseases of the vitreous and retina, with particular interest in the surgical management of macular disorders, including diabetic retinopathy, complex retinal detachments and trauma. Dr Deupree is a Fellow of the American Academy of Ophthalmology and the American College of Surgeons. He is currently Principal Investigator in a Phase III FDA clinical trial for a treatment for macular degeneration. He has recently opened solo practice and was previously Director of the St. Luke's Retina Institute for twelve years. Dr Deupree is an advisor on patient care and comfort, in addition to surgical knowledge and methodology. His retinal and vitreous knowledge complement the overall experience of the advisory board.

# Finian MacCana, B.Sc. (Hons), AMCT, FCOptom., M.Sc., FVCO, FAICD:

Mr. MacCana is a Fellow of the British College of Optometry, the Victorian College of Optometry and is a councillor with the Australian Institute of Company Directors. He is one of four founding members of Optomeves, a group of optometry businesses, and has been in private practice for over 30 years. Currently, Mr. MacCana is lecturing in the Department of Anatomy and Physiology at the University of Tasmania Medical School. He is a Director. of Diabetes Australia Tasmanian Division and other non-listed public companies, and a former Director of Laubman and Pank Holdings Ltd and is a consultant to national and global companies involved in eyecare. Mr. MacCana contributes strongly in the areas of science, medicine and commerce. His experience with previous companies and in practice is an asset to Regenera.

Philip Penfold, PhD: Dr Penfold is an authority on back of the eye disorders, having worked in the field of macular degeneration and diabetes-related retinopathies for over twenty years. In this time, Dr Penfold has published hundreds of articles in this field, in addition to coediting a recent textbook on macular degeneration. With a strong focus on the immune aspects of these diseases, he has opened the door for a number of treatment options and has patented several of these. His ongoing contributions as a specialist in the field are advancing Regenera's success.

# Upcoming Conference Presentations

# SERI-ARVO

## Regenera Group

Immunological aspects of AMD: Influence of immunity on barrier function.
PL Penfold, ML Taylor, J Thomas, WJ Ardrey

Disruptive, radical and incremental innovations in life sciences: winning strategies for ophthalmology. WJ Ardrey, YY Foong, EP Law, DR Sanders

# Regenera-Sponsored

WABRI

Characterisation and optimization of nanopolymeric particles in the treatment of diabetic eye diseases. X Le, GE Poinern, HAE Benson, Y Chen, G Dalwadi, WJ Ardrey

### ANU

A dopamine agonist mimics the effect of normal vision in preventing form-deprivation myopia. CS McCarthy, P Megaw, IG Morgan

 $\alpha\beta\text{-Crystalline}$  and retinoic acid receptor  $\text{-}\alpha$  in the myopic chicken.

R Ashby, P Megaw, B Walcott, IG Morgan

Muscarinic receptor subtypes involved in cholinergic control of excessive coular growth. P van Rijwijk, IG Morgan, P Megaw

How genetics is school myopia IG Morgan, KA Rose

## University of Melbourne

Establishing fast clinical tests of rod and cone adaptation in early age-related macular degeneration. JA Phipps, P Dimitrov, AJ Zele, RH Guymer, AJ Vingrys

Toward and animal model of AMD: functional losses induced by high cholesterol diets.

AJ Vingrys, AJ Zele, JA Phipps, EL Fletcher,
RH Guymer

## Tulane University

The effect of combinations of flurbiprofen, low molecular weight heparin and doxycycline on the inhibition of corneal neovascularization.

GA Peyman, AA Kazi, MR Esfahani, E Aydin, M Kivilcim DR Sanders

Inhibition of experimental angiogenesis of comea by doxycvoline.

DR Sanders, E Aydin, GA Peyrnan, MR Esfahani, AA Kazi

## ARVO

Tulane University

The effect of combinations of flurbiprofen, low molecular weight heparin and doxycycline on the inhibition of corneal neovascularization.

A Kazi, GA Peyman, MR Esfahani, E Aydin, M Kivlicim, DR Sanders

Prevention of comeal neovascularization: evaluation of various commercially available compounds in an experimental rat model.

MR Esfahani, GA Peyman, E Aydin, AA Kazi, DR Sanders

Combination of triamcinolone acetonide with low molecular weight heparin and doxycycline in inhibition of experimental corneal angiogenesis. M Kivlicim, E Aydin, GA Peyman, MR Esfahani, AA Kazi, DR Sanders

## ANU

M4 muscarinic acetylcholine receptors mediate muscarinic block of axial elongation in the chicken. IG Morgan, P van Rijswijk, P Megaw

## The Royal Hawaiian Eye Meeting - Retina

A sustained release preservative free triamcinolone preparation for intravitreal injection. DR Sanders

# Regenera in the news

In recent months, Regenera has been featured in a number of media publications and by various prestigious brokerage firms, investment banks and analyst groups. These are some of the selected highlights.

### The Australian Investor, 24 November 2004

Exciting Times for Regenera

"Regenera Lirnited (ASX:RGA) has commenced negotiations on its first commercialisation deal, which it hopes to conclude by the end of the calendar year. Regenera CEO, William Ardrey, is excited about the future of the eye disease company, with a string of positive announcements coming out in recent times."

### Shaw Stockbroking Report, 23 November 2004

Progress towards commercialisation and licensing deals

"RGA has made significant regulatory, commercial licensing and scientific progress to get its products on the market rapidly, for the treatment of eye diseases such as Age related macular degeneration (AMD), Diabetic retin

# ABN AMRO Morgans Biotech & Healthcare Weekly Snippets, 12 November 2004

"RGA, who develop treatments for diseases at the back of the eye (like diabetic retinopathy, diabetic macular edema and age-related macular degeneration), is making good progress."

# PricewaterhouseCoopers BioForum, Number 10, November 2004

"Anticipated milestones for Regenera in the upcoming quarter include the completion of a major commercial licensing transaction, and significant regulatory progress around an indication for the company's lead product. In addition, it is developing a more competitive capital structure via acquisition of the remaining minority shareholdings in Retmed Pty Ltd and the end-of-year launch of its planned American Depository Receipt program. Over 15 per cent of the company's shares are held by US investors, mostly ophthalmologists and medical professionals, with another significant holding in the hands of major Australian investors, including OIC and Australian Dexia."

## Australian Biotechnology News, 20 October 2004

Regenera receives ethics approval for second clinical trial

\*Perth's Regenera (ASX: RGA) has received ethics approval for the second of five Phase III clinical trial to be conducted in Singapore using intravitreal injections of its product Visagen to treat macular oedema."

### AusBiotech Newsletter. 6 August 2004

Regenera expands treatments for back of the eye diseases

"Sydney, Australia: 4 August 2004. Australian eyecare company Regenera (ASX: RGA) today announced that it had acquired new technology related to its core product Visagen(tm) from U.S-based group, MiNU LLC."

# Share Price Update

Market Capitalisation: Share Price: Option Price: \$37.1 million \$A0.51\* \$A0.10\*

ASX Code: RGA ASX Code: RGAO

### Kay Announcements

- "Update on RGA Offer to Retmed P/L Shareholders" (16 November 2004)
- "Offers to acquire remaining 100% of Retmed Pty Ltd" (21 October 2004)
- "Singapore Ethics Approval- Additional Phase III Visagen Clinical Trial" (20 October 2004) "Appoints top US Investigators to team" (27 August 2004)



11th January 2005

The Manager Company Announcements Australian Stock Exchange 4<sup>th</sup> Floor 20 Bridge Street SYDNEY NSW 2000

Dear Sir

The Directors of Regenera Limited wish to announce that our company register will be transferred to Advanced Share Registry Services, 7th Floor, 200 Adelaide Terrace, Perth WA 6000, Phone: 08 9221 7288, Facsimile: 08 9221 7869, at the open of business on 24<sup>th</sup> January 2005. Our register is currently maintained by ComputerShare Investor Services Pty Limited – Perth.

BY ORDER OF THE BOARD

Yours faithfully

STUART USHER
Joint Company Secretary

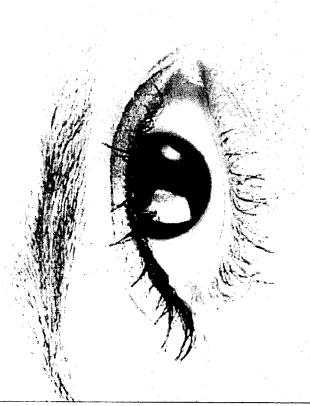
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# January 2005



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# Overview

- Successful IPO (June 2004) raised \$10.2m
- Acquires IP to develop treatments for diseases of the eye
- age-related macular degeneration (AMD)
- diabetic retinopathy (DR), and
- diabetic macular edema (DME)
- Experienced management team
- international experience commercialising health care and related technology
- World class scientific and medical advisors
- based in Australia and the U.S.

# International ophthalmic stocks have outperformed in 2004

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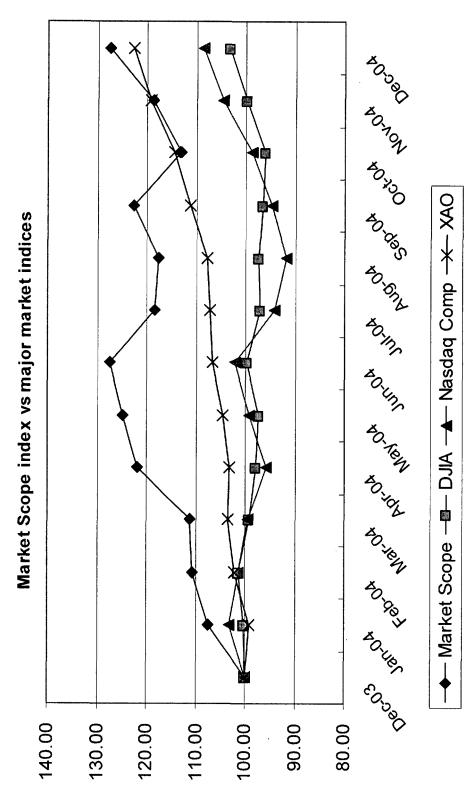
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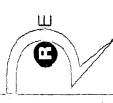
# Relative Performance



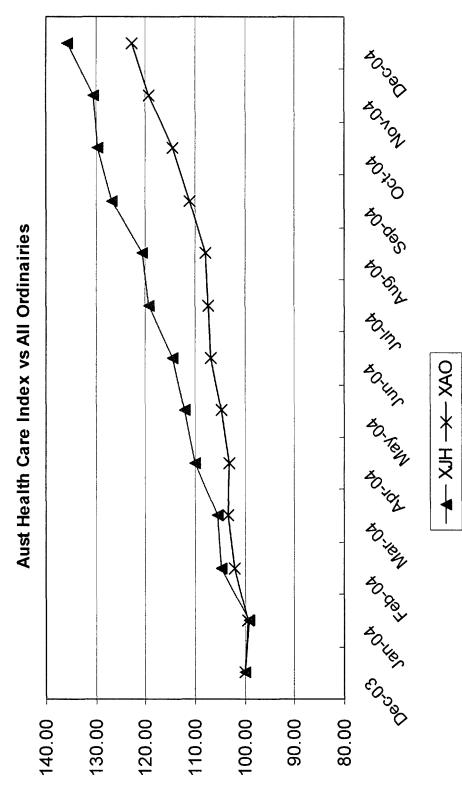
Note: Market Scope is a leading U.S journal that follows developments in the eye care industry. The index comprises 26 pharmaceutical companies primarily focused on treatments for ophthalmic conditions and located in Nth America and Europe.

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# Australian health care sector has outperformed over the last year







Note: The ASX Healthcare Equipment & Services index includes Cochlear and Resmed.



# Achievements since listing

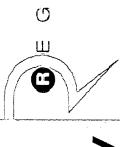
- Expanded target diseases from one indication to four
- Acquired strategically important IP and technology
- Increased Visagen product suite from three to six
- Established relationships with Singapore Eye Research Institute, Tulane University and others
- Achieved US FDA designation for Visagen V as a device
- Advanced licensing negotiation phase
- Successful issue of options

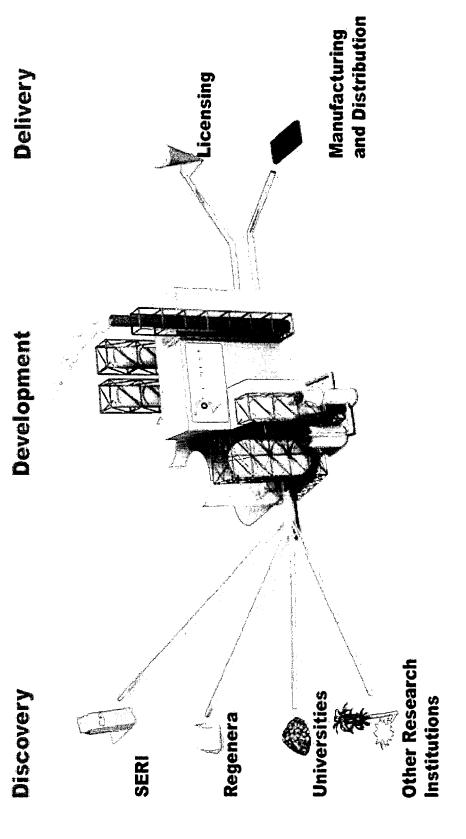
Shares have traded in a range of \$0.38 - \$0.60

# Vitrectomy video

# for visualisation in nseq Vitrectomy Visagen

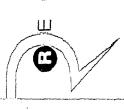
# development and drug delivery Drug discovery, drug





Research - Development - Commercialisation - Marketing/Licensing - Distribution - Improvements

# Focus on licensing products



Go to Market	Strategy	
Clinical Trials		Phase I Phase II Phase III
Pre Clinical	Development	
Research	And	Development

# Regenera's areas of activity

# Manage the development process

- Acquire IP supporting product development
- Outsource research & development
- Partnering for clinical trials
- Licensing of manufacturing, sales and distribution

# Benefits of business model

- Faster time to revenue
- Expense sharing
- Cash preservation

# Typical licensing deal

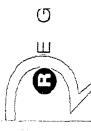
- \$ Cash upfront
- \$ Trials funded by partner
- \$ Royalty percentage of sales
- Performance based revenue milestones ᡐ



# Product summary

Product	Description
Visagen	Current off-label standard of care for back-of-the-eye diseases
Visagen V	Use of Visagen as a device in the surgical procedure Vitrectomy
Visagen SR	A sustained release version of Visagen
Visagen MR	Based on an alternate class of steroid  Extends the product range further into the diabetes segment
Visagen DH	Combination of steroid and other agents
Injection device	Designed for highly accurate guidance of intravitreal injections
	Device may be developed with a pre-filled dosage of Visagen

# Product development and status



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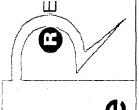
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SOF OF PATENT PRE-CLINICAL CLINICAL	R&D Formulation Lab Animals Phase 2 Phase 3							
PROOF OF PATE	R&D							
DRUG		Visagen PF	Visagen V-1	Visagen SR	Visagen MR	Visagen DH	Steroid Responder Kit	Injection Kil

# treatable with triamcinolone acetonide Annual incidence of target diseases









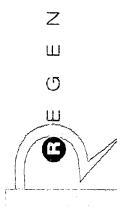
edema." ... We believe this reformulation for macular could be a \$US 100m "Triamcinolone opportunity..." Banc of America Securities research report 12 May 2004.

Target Indication		US (est)	Non US (est) Total (est)	Total (est)
Vitrectomy	Vitrectomy performed	207,000	218,000	425,000
Wet AMD	Annual incidence	217,000	220,000	437,000
Diabetic Macular Edema	Annual incidence	200,000	540,000	1,040,000
Cataract	Cataract surgery performed	1,500,000	1,530,000	3,030,000

Estimates of potential market size for triamcinolone acetonide to treat diseases of the eye - \$US 100m to \$US 200m p.a

# NASDAQ listed eye care company

Eyetech Pharmaceuticals, Inc.

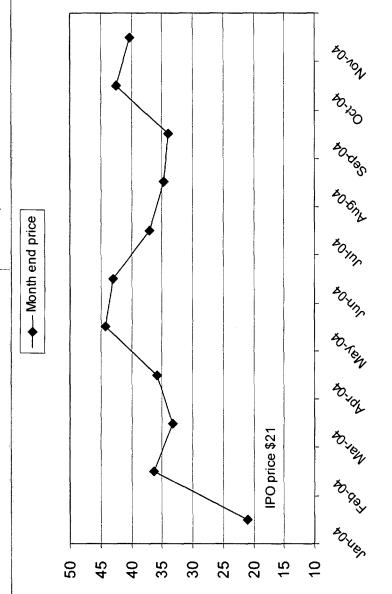


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# Summary details - \$US

- IPO in Jan '04
- 6.5m shares @ \$21.00
- Close on first day \$32.40
- Close on 26 Jan \$37.12
- Increase since IPO 76.8%
- Market Cap 26 Jan \$1.54b

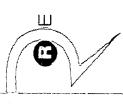


Pfizer, Inc. is the major global partner for Eyetechs product – Macugen

working on a drug to address blindness – deal potentially valued at \$US 527n Pfizer, Inc. has recently acquired Angiosyn, Inc. a biotechnology start up

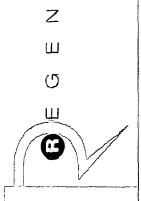


# Summary - Planning for success



- \$ Growing incidence of the target diseases
- \$ Large market for improved treatments
- \$ Visagen a proven product that works
- \$ Expanding IP and technology portfolio
- \$ World class scientific and medical advisory board
- \$ Strong product development pipeline
- \$ Advanced licensing and commercial discussions covering
- \$ products
- \$ geography
- \$ future product development, alliances and joint ventures
- \$ Expanding strategic alliances

# Forward looking statements and risks



companies future financial requirements, general economic conditions, differ materially from actual future events or results due to the range of based on managements current expectations. These statements may risks and uncertainties associated with the drug and medical device Australia and other countries including potential delays in obtaining This presentation may contain forward-looking statements that are development process including manufacturing and licensing, risks inherent in the regulatory approval process applicable in the U.S., approvals, market acceptance of the companies products, the and other risks and uncertainties. There can also be no assurance that competitors will not independently owned or licensed by Regenera or its subsidiary companies (Regenera develop similar products or processes that seek to circumvent patents Group), or that patents owned or licensed by Regenera Group will provide adequate protection or competitive advantage.

Nedlands, Western Australia 6009

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e: info@regenera.com.au

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27 January 2005

THE OF KITERMATICHA, COPPORATE FINANCE

Ms Christine Panetta Companies Advisor Australian Stock Exchange Limited Level 8, Exchange Plaza 2 The Esplanade PERTH WA 6000

**FACSIMILE: 9221 2020** 

Dear Ms Panetta

# **ASX QUERY**

I refer to your letter dated 27 January 2005 regarding an article published in the Australian Financial Review today (Article).

In response to your letter we confirm the following:

- As previously announced to Australian Stock Exchange Limited (ASX), the Company is in negotiations regarding commercial transactions involving its technology. Currently name of the negatiations have concluded and, accordingly, the Company has no information to announce to ASX regarding the Article.
- 2. The Company confirms that it is in compliance with the ASX Listing Rules and, in particular, ASX Listing Rule 3.1.

Should you have any queries please do not hesitate to contact me.

Kind regards

WILLIAM ARDREY

Chief Executive Officer

Regenera Limited



27 January 2005

Mr Stuart Usher Company Secretary Regenera Limited Ground Floor, 117 Stirling Highway NEDLANDS WA 6009

By facsimile: (08) 9389 5944

Dear Smart

Regenera Limited (the "Company")

RE: ARTICLE IN THE AUSTRALIAN FINANCIAL REVIEW

We refer to the article entitled "Renewed deal talk about Regenera" published in The Australian Financial Review on 27 January 2005 (the "Article", copy attached).

In light of the information contained in the Article, please respond to each of the following.

- 1. Please comment on the information contained in the Article in so far as it relates to the Company.
- 2. Please confirm that the Company is in compliance with the listing rules and, in particular, listing rule 3.1.

Your response should be sent to me on facsimile number (08) 9221 2020. It should not be sent to the Company Announcements Office.

Unless the information is required immediately under listing rule 3.1, a response is requested as soon as possible and, in any event, not later than the close of business (ie before 5.00 pm W.S.T.) on Thursday 27 January 2005.

The response must be in a form suitable for release to the market. If you have any concern about release of a response, please contact me immediately.

# Listing rule 3.1

Listing rule 3.1 requires an entity to give ASX immediately any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities. The exceptions to this requirement are set out in listing rule 3.1A.

Australian Stock Exchange Limited

Telephone 61 (08) 9224 0014

Facsimile 61 (08) 9221 2020 Internet http://www.esx.com.au

ABN 98 008 624 691

Exchange Plaza 2 The Esplanade Perth WA 6000

GPO Box D187 Perth WA 6940

Level 8

In responding to this letter you should consult listing rule 3.1 and Guidance Note 8 - Continuous Disclosure: listing rule 3.1.

If the information requested by this letter is information required to be given to ASX under listing rule 3.1 your obligation is to disclose the information immediately.

Your responsibility under listing rule 3.1 is not confined to, or necessarily satisfied by, answering the questions set out in this letter.

# Trading halt

If you are unable to respond by the time requested, or if the answer to question 1 is yes and an announcement cannot be made immediately, you should consider a request for a trading halt in the Company's securities. As set out in listing rule 17.1 and Guidance Note 16 – Trading Halts we may grant a trading halt at your request. We may require the request to be in writing. We are not required to act on your request. You must tell us each of the following.

- The reasons for the trading halt.
- How long you want the trading halt to last.
- The event you expect to happen that will end the trading halt.
- That you are not aware of any reason why the trading halt should not be granted.
- Any other information necessary to inform the market about the trading halt, or that we ask for.

The trading halt cannot extend past the commencement of normal trading on the second day after the day on which it is granted. If a trading halt is requested and granted and you are still unable to reply to this letter before the commencement of trading, suspension from quotation would normally be imposed by us from the commencement of trading if not previously requested by you. The same applies if you have requested a trading halt because you are unable to release information to the market, and are still unable to do so before the commencement of trading.

If you have any queries regarding any of the above, please let me know.

Yours sincerely

Christine Panetta

Senior Companies Adviser

Direct Line: (08) 9224 0014

# Street Talk

The resily emering part is that Pormet's outlays for his state look to be only 60 suffice on the basis that the Tim's share of his options are exercisable at 6%. (I oversy, his sold buy million shares at 550 fact year, so he managed to take all proteins 61.4, selfice, 9

# Suncorp trades spor takeover talk

Door across gainst saw orang NELA besiness in Suncerp shares on Tomolog, crossing two lines of stock worth a total of \$44.5 million.

es consumed account to reignite specialistics that investors anoth finally see some income might finally see some more pulsecesse in the financial services

And there has been talk in recent weeks that Westpac is evening off the Brisbane-based general insurance

and banking group.
The lines of 1.5 million and

The lines of LS militors and ! million Sunsury sharets were crossed at \$517,00, of the company's high of \$18,23 on Sunsury 13. In which such a strong run from \$14 last August, Sunsury boas John Methody has almost pasced himself over of the market, though the dream conclusions remains a marger with \$5 George, diversifying the latter's building exposure into Operational. The tally may, of consequent reflect the personal increases sector. Op \$6 last also seen survey are discussed in the state of the personal increases sector. Op \$6 last also seen survey are discussed in the state of the sector. Op \$6 last also seen survey are discussed to promise the set of the sector. Op \$6 last also seen survey are discussed for possible rises in the survey and the sector of \$60 last also well placed for possible rises in \$10 imprest trues, times about in \$10 imprest trues, times about

is also well placed to peace to their in US interest rame, since about 30 per cent of its insumpostences are backed by US doğur cash and finad-interes securities. Every I per cent increase in raises adds about

\$28 million to the betters line.

Among the other rumous strong the market on Toesday was talk that Patrick Corporation might actually have a bending facility is place to bendered the buyout of the rest of

benkroll the bayout of the rest of Vigin Blue. Vigin Blue. Vigin Blue recovered fat to \$1.76 on Tuesday, but that might have more to do with those who think has work's lower profit revision by boss Brett Coeffrey was the result of a short-term east overcupantly problem that will be eventually contained.

problem that will be eventually sorted out.

Elsewhere, Country Road ticked up 26s to 52.28 on thin volume, and epocularion comments that 11.85 per cent than the country Road out to the country of the our make another play for control,

# Fortescue a model miner for Forrest

ne Merale Group ebairman Perfective Metals Group exhibition Andrew Porrest has set the semplate for creating a \$100 million resources house without histing to produce any estmines or physically sell a A OF MITY OTE

The most roccus set of accounts shows the company made a \$600,000 loss in the most recent half,

\$600,000 loss in the morr seems in it. but ther; not to say Fortescue's Chichester Ranges into ove project in the Palbers wages went's evennually grove its worth of As for as Pattess is concerned it already has Thank; to Manday's reass options energies and the company's consistent news flow, the former Associate North SIAT million or the equivalent of almost half of Portugesce 's marker capitalisation,

the optivalent of demost half of Fortuscan's market capitalisation. With the letter rise in the share price to \$2.28 following a \$40 million convertible note raising. Fortuscan is now worth more than the stablished Pontson Mining, which is under hid by US run ore player Clevaland-Cliffs.

The really amazing part is that — [444 was repersed]

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# Media players line up for new Senate

Of macla takenover activity inter this year waters by reactive, the treated levels bulge spenutried, the state prices of ratios attacks in the sector could, in some cases, still leave saction 50 per cent to year.

THE SHOW'S NOT DUEP YET

dactions 50 per court to 1911.
That point is well libertrated by a Could Scalese Piret Roston analysis this week Clast looks at the potential for price gitten in access of the rises of clast looks to the rises of t

argon the October of recess emercial. However, the terril creek in their the releasing of creek made and funding screeking rates worth through well after lady, when the new Americans and backlings a cartainty. Also, there is an appetite for saler

"all-pearshart" sorty mergers (account than call it birs) and sorty media.

Demogration wiff the productors rather than proy and so won't have a transcript providers half byte their transcript providers in high pictures. ehare priors.

ther point of couries in that the Annount poers or causing part the multiples paid in the part there is a limit book of the part there is another too high, must there is another passing or companies now to do dading the causing per steps.

Apart from the well-seried

sparting the welf-period desiration for Februaries a margar of the Tun Networker a taken-ne hy-Publishing it invocaming List, other invested Sanis Incinde Tee hidding for Austrean, Rural Press.

bibling for Prime Television or Sections Cross (though Seatter Cross seaths to view has it as an section) and West Australia; Neurospans buying Prima Televi Pairins (trungerseat seases be

as assers keep presinter, but as a well-d oute by IP Morgan's Other swengthad this work, man in the carriers, had ading some of its major investors like Perputsal Investoration consideration

Perpetusi became e major altarchoider in October, the tir algueilles that its investment neut le

# Renewed deal talk about Regenera

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it dessa't happen of ea for Australian blomchmology companies, but there is talk again that flagment is close to eating a multimillion-dollar licensing deal in the United States for its

the temper regime for in transmissions accessibly product, an side in retinal empty.

The company's leading product, Visigns, or injectible treatment for agency and dishest-regime ratios (AMD) and dishest-regime where of the eye" disease, is extracting increasing amoration overseas.

Rey Ragoners executives are in

increasing amortion overheas.

Rey Rageners executives are in the US.

The biotoch relead \$10 million in an instal public offering in June last year, but the stock has deen just to examinescent, trading within a range of 50c to 50c, warrains 50c lious price.

More than 50 per cent of the funds vision of several case to execute a 51 per cent stake in the University of Sydney sheeland Returned, which owns the rights to Viengen, and to found the meet round of clinical trails. A medical breathrough in this area could pour hundracts of wallions of follows into a computing a collect pour hundracts of wallions of follows into a computing coffees. Als D is the most common and debilioning back of the eye disease and the leading course of bindness unang people aged 50 cemers in developed countries.

Lisabeter relaxed eye diseases include disbedie retrangenty, the leading course of bindness for adolument 50.

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umder 50.
Mennyhila, CSL's 5 per cent share price tilde in the particul days sony price tilde in the particule days may just be a partial numeroment of a little per cent tipe over the part three words, are then was notice in terret in the commentary by Mentic & Co, which reported is interim mentic on Treaster within the interior mentic on Treaster within Merch is developing a himma papellones visus vaccine in a joins wannes with USLs, a perior that has interested in importance for Merch shoot less years county without pale of in arthritis drug. Victor Maris more party years could with the vice with the could be an extend to file the vaccine with the US Food and Dang Administration to the second half of Administration in the second half of the year, it will be used to make grainal

# Acquisition may be in the pipeline for flush Rinker

As usual, there's plenty of curcest about the strength of the Milding sector, but you could burnly full by looking at the story were of trajectory of sixures to temper (SR construction quaterists are Risks which photosid at \$3.0.75 or Treats

non-sequential construction sectors fined gestring in contract term the learns this limitality of couling litters will selecte this decarter. In the US and Australia is now that

in the US and Australia is how chan composation fring for any skinedows in impellag in Architetta.

On Machineria Equither' sumbets, Philose is Bissly to between third-guarden agentage before behaver third-guarden agents \$10.00.5 million, beginning to that of rebooks \$10.00.5 million, beginning transferding growth in the US constitution of mose than \$20 per count. estions of more than 30 per cent En \$153.5 milles (\$39.6 milles loss on last month's sale of the



presidence operate operations in exchided.

Strong US content in branch to the key littler state of Forther suggest operations demand is high and the overgony should have OVERCOME II BUSTOWNS OFFICERS

Nowther Binker has mailined about

450 million from the anie of its US

430 million from the sale of the US-polyphin operation, its clots develouse low and spectian hand of industry councilation in survier way. Rinker to the for survier that whice it is belond its several target of it is behind its second target of \$1,5200 million in social-tions, and travity back its states in not

क्षेत्र प्रस्ती हुए दशक हैत क्षर्यक्रमध्यान है Portest's outlay for his state appears to be only if million on the basis that the lion's share of his options were compleable at Se. And he sold 2 million shares at 55c last year, so he managed to take off mother \$1.1 million, heaving a \$7 million order.

57 million cuties.

Aftery of change of director's harms include for Ferniet and his follow directors were fired off entire two weeks would not be change, but it's guine a task to receive the numbers with the group's previous ASK filings.

Former's harries shows in its new source of a self-time of 25 willions.

nodilar 28 FB (anotrone as testimos scripted in additional to 35 million shares in Fortagene chrough the starctice of options, taking his inscret to 100,85 million shares out of 2173 million on these, As a result, Portest to longer halds my options in Fortages, However, an

announcement uries to the optic recies India ed that Bore archevent interest to \$5.55 million opcione, so there appears to be an unexplained shortfall of 1,71 million

abares.
The latest needes for fellow director Greene Rowley shows be increased his shareholding in Portague by I million there through the councies of emilio coming \$20,000 or 86 meds. B rt. Bruz county saturate or an early. But Fortacours is 2004 annual report stated that Rowley did not hold any relevant interpret in any options. Given the 8e exercise price, it is possible that Forness transferred his possions tract current transferred as relevant incorrect in 1 millions & options to Roydey. However, that transfer (if it did deour) has not been disclosed previously. Portrest had been quoted as saying Portresto was now "options (see", leaving it with a cleaner ownership.

Fructure. The number of options has indeed fallow approximately, but these are acreally 2,500,000 immerciated options in Persuants. It appears 500,000 of these are held by dronour Calin Linepan. The other 2 million are held by orugioness of Perusants, with a concentral tripler exercise price of \$2.5 at these \$2.67 a share. With the exception of Lingues,

and the discrepancy with respect to the Perrest options memioned earlier, it is true that none of the directors of Pertescen new bold my options, including 250,000 options with a fil exercise price that appear to have been exercised by other directors, with these shares remaining in eacrow until Negember 25.

Yesterday Pomest was promoting the prospects of the other company he chairs, Hibernia Gold.

# Word from US **just bad timing**

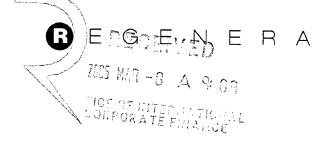
sew grawlf, teles2 mentle Administ fair week that he step on the wast from the ASX over the Peet Group fleet was nothing to do with any 'callural' influences from its New York shareholder.

New York informatic timing, then, then in Transday night the US Securities and Embange Commission fixed a civil authorized exprinish shorten to the two Grant allocations as also over the two Grant allocation of stockto institutional cilients in flour in 1999 and 1000.

The firms were a pay a SUS40 million (\$52 million)

penalty.
The conduct here counted a tisk of

meinformation about the demand for an IPO," the SEC and, Sound familiar?
Here, CSIPW postmo strife for offering a secret means to the suphisticated clients prepared to most up the shortful in least year's heat Bost, giving institutional and renal es the impression the floor was



# **REGENERA LIMITED**

(ABN 35 107 371 460)

# HALF YEAR FINANCIAL REPORT 31 DECEMBER 2004

# CONTENTS

Directors' Report	<u></u> 3	3
Statement of Financial Performance	7	
Statement of Financial Position	8	,
Statement of Cash Flows	9	,
Notes to and Forming Part of the Financial Stater	nents 10	ļ
Directors' Declaration	14	
Independent Review Report to the Members	15	
CORPORATE DI	RECTORY	
DIRECTORS	AUDITORS	
Mr Tony Fitzgerald - Executive Chairman Dr William Ardrey IV - Chief Executive Officer Mr Finian MacCana - Non Executive Director Mr Stephen Newman - Non Executive Director	HLB Mann Judd Chartered Accountants 15 Rheola Street West Perth WA 6005 Tel: +61 8 9481 0977 Fax: +61 8 9481 3686	
JOINT COMPANY SECRETARIES	SHARE REGISTRY	
Mr Evan Cross Mr Stuart Usher	Advanced Share Registry Services Level 7, 200 Adelaide Terrace Perth WA 6000 Tel: +61 8 9221 7288	
REGISTERED AND PRINCIPAL OFFICE	Fax: +61 8 9221 7869	
Suite 1 117 Stirling Highway Nedlands WA 6009 Tel: +61 8 9389 5933 Fax: +61 8 9389 5944	WEBSITE AND EMAIL ADDRESS  www.regenera.com.au Email: admin@regenera.com.au	
SOLICITORS	CORPORATE ADVISER	
Steinepreis Paganin Lawyers & Consultants Level 4, Next Building 16 Milligan Street Perth WA 6000	HealthTec Growth Partners Pty Ltd Suite 1, 117 Stirling Highway Nedlands WA 6009 Tel: +61 8 9389 5933 Fax:+61 8 9389 5944	

# **DIRECTORS' REPORT**

The Directors present their report together with the consolidated financial statements of Regenera Limited, comprising the Company and its controlled entities, for the half year ended 31 December 2004.

## DIRECTORS

The names of the Directors who held office during the half-year and up to the date of this report:

Mr Tony Fitzgerald — Executive Chairman

Dr William Ardrey IV — Chief Executive Officer

MrFinian MacCana — Non Executive Director

Mr Stephen Newman – Non Executive Director

# **REVIEW OF OPERATIONS**

Since listing in June 2004, Regenera has cemented its position as a developer of retinal pharmaceutical products. In pursuing the objectives outlined in the prospectus, it has sought to expand its existing intellectual property portfolio, broaden its product range and pursue commercial collaborations with reputable research and industry partners.

# Key areas of progress during the past six months include:

# <u>Acquisition of Complementary Triamcinolone Acetonide (TA) Technology:</u>

The Regenera Group holds an issued U.S patent for the use of the steroid triamcinolone acetonide (TA) for the treatment of macular degeneration (the Visagen family of products). In August 2004 Regenera Group acquired three significant additional items of TA related technology from a U.S based healthcare investor group. The most significant additional item acquired was an issued U.S patent for the use of TA in the surgical procedure called vitrectomy. This has the potential to provide Regenera with a rapid method of bringing the first approved ocular indication of TA into the U.S market.

# Further Patent Filings:

In addition to Regenera's two granted U.S patents for the use of TA in the eye, the company holds other intellectual property relating to the use of TA either stand alone or in combination with other drugs for the treatment of retinal diseases. In order to strengthen the company's intellectual property portfolio which underpins its pipeline products, it has recently filed international patent applications to provide additional coverage in a range of countries primarily for Visagen SR, Visagen DH and Visagen when used as a predictor of high intraocular pressure.

# Relationships with Leading Eye Care Institutions:

Regenera has established a collaborative research relationship with Singapore Eye Research Institute (SERI) who manages various aspects of preclinical studies for several Visagen based products. Monash University, through the Victorian College of Pharmacy, has been an effective partner in supporting development of various formulations of Visagen SR, the sustained release version of Visagen designed for less frequent usage. A number of other valuable research collaborations have been put in place with leading scientists and individual clinics in the U.S.

# Regulatory Affairs:

Late in 2004, the U.S Food and Drug Administration (FDA) agreed to designate Visagen V as a medical device (not as a drug) when used in the eye surgery procedure called vitrectomy. This designation will be helpful to accelerate regulatory approval for the first ocular indication of TA in the U.S. Since being notified of this designation, the company has been preparing a Pre-Market Approval (PMA) submission for the FDA in order to obtain regulatory approval in the U.S. for the vitrectomy product. Based on the U.S FDA designation it has presented to the Therapeutic Goods Administration (TGA) in Australia for designation of Visagen V as a device and their response is anticipated in the first quarter of 2005. If the TGA also designate Visagen V as a device, then there will be a strong case to support a similar designation in the European Union countries.

Regenera has also recently filed an application with the TGA for a medical device designed to improve the ergonomics and effectiveness of an ocular injection.

# Commercialisation:

Regenera has been actively pursuing commercial licensing opportunities with appropriate partners for some of its products to address the substantial unmet medical need for improved treatments for the target retinal diseases. Its ocular drug technologies have been validated at major industry conference presentations and in ophthalmology journal articles. This industry validation assists in generating market interest in Regenera's products.

# Acquisition of Minority Interests in Retmed Pty Ltd:

In November 2004, Regenera acquired the remaining 49% of Retmed Pty Ltd, the subsidiary company that held the original TA related patents developed at the University of Sydney. The company issued a total of 22.42 million shares and 5.9 options to the Retmed shareholders in consideration for the acquisition of all of their Retmed shares. The buy out of the minority interests in Retmed will enable Regenera to fully capture the value of any transactions which may arise out of the commercialisation of the patented technologies owned by Retmed.

# Market and Industry Outlook

In the second half of 2004, Macugen (a product from Eyetech Pharmaceuticals, Inc. and Pfizer) was approved by the U.S FDA for the treatment of some forms of age related macular degeneration. This drug entered the market in the US in early 2005.

Prior to the approval of Macugen, the only approved treatment for AMD was Visudyne photodynamic therapy from QLT, Inc. and Novartis.

There are also drugs in development from other major ophthalmology companies which will be seeking approval from the FDA over the next year or so. These include Retaane from Alcon Laboratories, Inc. and Lucentis from Genentech, Inc.

Regenera believes that the markets for the treatment of AMD, DME, and DR will continue to grow strongly and that there will be significant market demand for Visagen and a range of new drugs expected to enter the market between 2005 and 2010.

# **Operating Results**

For the six months to 31 December 2004, the consolidated net loss of the company after tax and outside equity interest was \$2,052,051. This result included goodwill amortisation expense of \$154,719.

# Auditors' independence declaration

A copy of the auditors' independence declaration as required under section 307C of the Corporations Act 2001 is set out page 6 and forms part of this directors' report.

Signed in accordance with a resolution of the Board of Directors:

Mr Tony Fitzgerald
Executive Chairman

Perth, 28 February 2004



# Auditors' Independence Declaration

As lead auditor for the review of the financial report of Regenera Limited for the half year ended 31 December 2004, I declare that to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Regenera Limited.

Perth, Western Australia 28 February 2005

L DI GIALLONARDO Partner, HLB Mann Judd

# CONSOLIDATED STATEMENT OF FINANCIAL PERFORMANCE FOR THE HALF-YEAR ENDED 31 DECEMBER 2004

	Notes	Consolidated 31 December 2004 \$
Revenue from ordinary activities	2	146,347
Employee benefits expense	•	(585,766)
Consulting and professional services		(758,399)
Depreciation and amortisation		(159,697)
Statutory and compliance		(49,484)
Marketing		(71,313)
Travel		(287,135)
Research and development		(611,121)
Other expenses from ordinary activities		(193,726)
Loss from ordinary activities before income tax	•	(2,570,294)
Income tax expense relating to ordinary activities		-
Net loss from ordinary activities after income tax	•	(2,570,294)
Net loss attributable to outside equity interest		518,243
Net loss attributable to members of Regenera Ltd	•	(2,052,051)
Total changes in equity other than those resulting in transactions with owners as owners	•	(2,052,051)
	·	-
Rasic parnings per share (cents per share)		(4.5)

Basic earnings per share (cents per share) (4.5)

This consolidated statement of financial performance is to be read in conjunction with the notes to the half-year financial statements set out on pages 10 to 13.

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2004

		Consolidated
	Notes	31 December
		2004
		\$
Current Assets		
Cash assets		5,376,359
Receivables		299,489
Other		112,807
Total Current Assets		5,788,655
Non Current Assets		
Property, plant and equipment		145,293
Intangible assets	3	13,850,553
Total Non Current Assets		13,995,846
Total Assets		19,784,501
Current Liabilities		
Payables		491,718
Provisions		45,901
Total Current Liabilities		537,619
Total Liabilities		537,619
Net Assets		19,246,882
Equity		
Contributed equity	4	22,057,934
Option reserve		101,462
Accumulated losses	5	(2,912,514)
Total Equity		19,246,882

This consolidated statement of financial position is to be read in conjunction with the notes to the half-year financial statements set out on pages 10 to 13.

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE HALF-YEAR ENDED 31 DECEMBER 2004

Interest received 146,347 Payments to suppliers and employees (2,024,387)  Net cash provided by/(used in) operating activities (1,878,040)  Cash flows from investing activities  Cash paid on acquisition of controlled entity (2,000,000) Payments for property, plant and equipment (46,826) Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Cash flows from operating activities	Consolidated 31 December 2004 \$ Inflows/(Outflows)
Payments to suppliers and employees (2,024,387)  Net cash provided by/(used in) operating activities (1,878,040)  Cash flows from investing activities  Cash paid on acquisition of controlled entity (2,000,000) Payments for property, plant and equipment (46,826) Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities  Proceeds from issue of securities Proceeds from issue of securities  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	<b>3 3 3 3 3 3 3 3 3 3</b>	
Net cash provided by/(used in) operating activities  Cash flows from investing activities  Cash paid on acquisition of controlled entity (2,000,000) Payments for property, plant and equipment (46,826) Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities  Proceeds from issue of securities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Interest received	146,347
Cash paid on acquisition of controlled entity (2,000,000) Payments for property, plant and equipment (46,826) Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities  Proceeds from issue of securities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Payments to suppliers and employees	(2,024,387)
Cash paid on acquisition of controlled entity (2,000,000) Payments for property, plant and equipment (46,826) Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities  Proceeds from issue of securities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Net cash provided by/(used in) operating activities	(1,878,040)
Payments for property, plant and equipment (46,826) Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities  Proceeds from issue of securities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Cash flows from investing activities	
Payments for property, plant and equipment (46,826) Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities  Proceeds from issue of securities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Cash paid on acquisition of controlled entity	(2.000.000)
Payments for research and development (537,058) Payments for intellectual property (236,242) Cash introduced on acquisition of controlled entity 112,000  Net cash provided by/(used in) investing activities (2,708,126)  Cash flows from financing activities  Proceeds from issue of securities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	·	• • • •
Payments for intellectual property Cash introduced on acquisition of controlled entity  Net cash provided by/(used in) investing activities  Cash flows from financing activities  Proceeds from issue of securities Payments for share issue costs  Net cash provided by/(used in) financing activities  Net increase in cash held Opening cash balance  (236,242) 112,000  (2,708,126)  (10,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (2,708,126)  (3,26)		, , ,
Net cash provided by/(used in) investing activities  Cash flows from financing activities  Proceeds from issue of securities Payments for share issue costs  Net cash provided by/(used in) financing activities  Net increase in cash held Opening cash balance  (2,708,126)  (101,462 (68,226)  (68,226)  (4,552,930) (4,552,930) (9,929,289)	·	,
Cash flows from financing activities  Proceeds from issue of securities 101,462 Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Cash introduced on acquisition of controlled entity	112,000
Proceeds from issue of securities  Payments for share issue costs  Net cash provided by/(used in) financing activities  Net increase in cash held  Opening cash balance  101,462 (68,226)  (68,226)  (4,552,930) (9,929,289)	Net cash provided by/(used in) investing activities	(2,708,126)
Payments for share issue costs (68,226)  Net cash provided by/(used in) financing activities 33,236  Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Cash flows from financing activities	
Net cash provided by/(used in) financing activities  33,236  Net increase in cash held  Opening cash balance  (4,552,930)  9,929,289	Proceeds from issue of securities	101,462
Net increase in cash held (4,552,930) Opening cash balance 9,929,289	Payments for share issue costs	(68,226)
Opening cash balance 9,929,289	Net cash provided by/(used in) financing activities	33,236
· · · · · · · · · · · · · · · · · · ·	Net increase in cash held	(4,552,930)
Cash at 31 December 2004 5 376 359	Opening cash balance	9,929,289
5,57 5,500	Cash at 31 December 2004	5,376,359

This consolidated statement of cash flows is to be read in conjunction with the notes to the half-year financial statements set out on pages 10 to 13.

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE HALF-YEAR ENDED 31 DECEMBER 2004

# 1. BASIS OF PREPARATION OF HALF-YEAR FINANCIAL REPORT

# (a) General

The general purpose half-year consolidated financial report has been prepared in accordance with the requirements of the Corporations Act 2001, Accounting Standard AASB 1029 "Interim Financial Reporting", Urgent Issues Group Consensus Views and other authoritative pronouncements of the Australian Accounting Standards Board.

It is recommended that this financial report be read in conjunction with any public announcements by the Company during the half year in accordance with continuous disclosure obligations arising under the Corporations Act 2001.

For the purpose of preparing the half- year financial report, the half-year has been treated as a discrete reporting period.

The half- year report does not include full disclosure of the type usually included in an annual financial report.

It is recommended that this financial report be read in conjunction with the annual financial report for the year ended 30 June 2004 and any public announcements made by Regenera Limited and its controlled entities during the half-year in accordance with continuous disclosure requirements arising under the *Corporations Act 2001*.

The accounting policies have been consistently applied by the entities in the consolidated entity throughout the half-year. The consolidated entity's accounting policies are consistent with those of the previous financial year (30 June 2004).

# The consolidated entity has also adopted the following accounting policies:

# (i) Acquisition of assets

The cost method of accounting is used for all acquisitions of assets regardless of whether shares or other assets are acquired. Cost is determined as the fair value of the assets given up, shares issued or liabilities undertaken at the date of acquisition plus incidental costs directly attributable to the acquisition.

# (ii) Comparatives

No comparative balances are required to be presented due to the first-time requirement to adopt Accounting Standard AASB 1029 "Interim Financial Reporting".

# (iii) Principles of consolidation

The consolidated financial statements incorporate the assets and liabilities of all entities controlled by Regenera Limited ("company" or "parent entity") as at 31 December 2004 and the results of all controlled entities for the year then ended. Regenera Limited and its controlled entities together are referred to in this financial report as the consolidated entity. The effects of all transactions between entities in the consolidated entity are eliminated in full. Outside equity interests in the results and equity of controlled entities are shown separately in the consolidated statement of financial performance and statement of financial position respectively. Where control of an entity is obtained during a financial year, its results are included in the consolidated statement of financial performance from the date on which control commences.

Page 10

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE HALF-YEAR ENDED 31 DECEMBER 2004

				Consolidated 31 Dec 2004 \$
2.	Revenue from operating activities Interest received			146 247
	merest received			146,347
				146,347
3.	Intangible assets			
	Goodwill on consolidation			13,594,388
	Accumulated amortisation			(154,719)
			_	
	Total		_	13,439,669
	Licenses and patents – at cost			410,884
	Total intangible assets			13,850,553
				\$
4.	Contributed equity			
	Issued and paid-up capital			
	Ordinary shares			22,057,384
	Incentive shares		_	550
			_	22,057,934
	Movements during the period:			
	wovements during the period.	No. of shares	Issue price	\$
	Ordinary shares:			
	Balance at beginning of half year	39,999,666	-	11,447,623
	Issue on acquisition of intellectual property	250,000	\$0.45	112,500
	Issue on 100% acquisition of Retmed Pty Ltd	22,420,000	\$0.468	10,500,000
	Conversion of Class C incentive shares	10,000,000	\$0.00001	100
	Share issue expenses			(2,839)
	Balance at end of half-year	72,669,666		22,057,384
	Incentive shares:			
	Balance at beginning of half year	65,000,000		650
	Conversion of Class C shares	(10,000,000)		(100)
	Balance at end of half-year	55,000,000		550
	Total	127,669,666		22,057,934
		*		

..........

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS (Cont') FOR THE HALF-YEAR ENDED 31 DECEMBER 2004

_	A a compositate della conse	Consolidated 31 Dec 2004 \$
5.	Accumulated losses	(960.462)
	Opening balance	(860,463)
	Net loss attributable to the members of Regenera Ltd	(2,052,051)
	Balance at the end of the half-year	(2,912,514)

# 6. Events subsequent to balance date

There were no items, transactions or events of a material nature that have arisen since the end of the half-year that, in the directors' opinion, would affect the financial position or results of the consolidated entity in future periods.

# 7. Controlled entities

Controlled entities of Regenera Limited at 31 December 2004:

Name	Country of Incorporation	% Owned
Retmed Pty Ltd	Australia	100%
Regenera USA Inc	USA	100%

On 1 July 2004 Regenera Limited exercised its two call options to acquire further shares in Retmed Pty Ltd which facilitated the acquisition of a further 27.1% of the issued shares in Retmed Pty Ltd representing an additional 20% to 51% voting entitlement and taking its equity to 44.39%. In December 2004 the company acquired the remainder of the issued capital of Retmed Pty Ltd. Consideration for the acquisition was the issue of 22.4 million Regenera Ltd shares at a fair value of 47 cents per share and 5,900,000 options at a nil fair value.

# 8. Segment reporting

The sole activity of the company is in the area of ophthalmology and has, via its project company Retmed Pty Ltd, developed in Australia a treatment specifically for diseases of the back of the eye such as Age related Macular Degeneration and Diabetes Related eye diseases and as such, represents only one reportable business and geographical segment.

# 9. Capital commitments

At the date of this report, the company does not have any capital commitments not otherwise disclosed in the financial report.

# 10. International Financial Reporting Standards

Australia is currently preparing for the introduction of International Financial Reporting Standards (IFRS) effective for reporting periods commencing on or after 1 January 2005. This requires the production of accounting data for future comparative purposes at the beginning of the next financial year. Entities complying with Australian equivalents to IFRS for the first time will be required to restate their comparative financial statements to amounts reflecting the application of IFRS to that comparative period.

All financial information disclosed in this half year financial report has been prepared in accordance with generally accepted accounting principles in Australia ("Australian GAAP").

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS (Cont') FOR THE HALF-YEAR ENDED 31 DECEMBER 2004

# 10. International Financial Reporting Standards (Cont'd)

The company's management and Board are assessing the significance of these changes and preparing for their implementation. An IFRS committee has been established to oversee and manage the company's transition to IFRS. We will seek to keep stakeholders informed as to the impact of these new standards as they are finalised.

The company's management and Board are of the opinion that the key potential implications in the company's accounting policies which will arise from the adoption of IFRS are:

# Taxation

Under IFRS, tax assets and liabilities are recognised using the balance sheet approach rather than an income statement approach. In addition, tax assets are recognised when recovery is probable rather than assured beyond reasonable doubt and/or virtually certain. This will result in a change to the current accounting policy, under which deferred tax balances are determined using an income statement method, items are only tax-effected if they are included in the determination of pre-tax accounting profit or loss and/or taxable income or loss and current and deferred taxes cannot be recognised directly in equity.

# Impairment of assets

The company currently determines the recoverable amount of an asset on the basis of undiscounted net cash flows that will be received from the asset's use and subsequent disposal. In terms of AASB 136 "Impairment of Assets", the recoverable amount of an asset will be determined as the higher of fair value less costs to sell and value in use. It is likely that this change in accounting policy will lead to impairments being recognised more often than under the existing policy.

# Equity-based compensation benefits

Under AASB 2 "Share Based Payment", equity-based compensation to employees will be recognised as an expense in respect of the services received. This will result in a change to the current accounting policy, under which no expense is recognised for equity-based compensation.

#### **DIRECTORS' DECLARATION**

The Directors of Regenera Limited declare that;

- 1. the financial statements and notes set out on pages 7 to 13:
  - (a) comply with Accounting Standard AASB 1029: Interim Financial Reporting and the Corporations Regulations; and
  - (b) give a true and fair view of the consolidated entity's financial position as at 31 December 2004 and its performance for the half year ended on that date.
- 2. In the directors' opinion there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Board of Directors:

Tony Fitzgerald Executive Chairman

Perth, 28 February 2005



#### **INDEPENDENT REVIEW REPORT**

# To the members of REGENERA LIMITED

# <u>Scope</u>

The financial report and directors' responsibility

The financial report comprises the statement of financial position, statement of financial performance, statement of cash flows, accompanying notes to the financial statements and the directors' declaration of Regenera Limited for the half-year ended 31 December 2004. The financial report includes the consolidated financial statements of the consolidated entity comprising the company and the entities it controlled at the end of the half-year or from time to time during the half-year.

The directors of the company are responsible for preparing a financial report that gives a true and fair view of the financial position and performance of the company and that complies with Accounting Standard AASB 1029 "Interim Financial Reporting", in accordance with the Corporations Act 2001. This includes responsibility for the maintenance of adequate accounting records and internal controls that are designed to prevent and detect fraud and error, and for the accounting policies and accounting estimates inherent in the financial report.

## Review approach

We conducted an independent review of the financial report in order to make a statement about it to the members of the company, and in order for the company to lodge the financial report with the Australian Stock Exchange and the Australian Securities and Investments Commission.

Our review was conducted in accordance with Australian Auditing Standards applicable to review engagements in order to state whether, on the basis of the procedures described, anything has come to our attention that would indicate that the financial report is not presented fairly in accordance with the Corporations Act 2001, Accounting Standard AASB 1029 "Interim Financial Reporting" and other mandatory professional reporting requirements in Australia and statutory requirements, so as to present a view which is consistent with our understanding of the company's financial position and of its performance as represented by the results of its operations and cash flows.

A review is limited primarily to inquiries of company personnel and analytical procedures applied to the financial data. These procedures do not provide all the evidence that would be required in an audit, thus the level of assurance is less than given in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion.

HLB Mann Judd (WA Partnership)
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Partners: Ian H Barsden, Terry M Blenkinsop, Litsa Christodulou, Wayne M Clark, Lucio Di Giallonardo, Colin D Emmott, Trevor G Hoddy, Norman G Neill, Peter J Speechley

(cont'd)

# Independence

In conducting our review, we followed applicable independence requirements of Australian professional ethical pronouncements and the Corporations Act 2001.

#### Statement

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the financial report of Regenera Limited, is not in accordance with:

- (a) the Corporations Act, including:
  - (i) giving a true and fair view of the consolidated entity's financial position at 31 December 2004 and of its performance for the half-year ended on that date; and
  - (ii) complying with Accounting Standard AASB 1029 "Interim Financial Reporting" and the Corporations Regulations 2001; and
- (b) other mandatory financial reporting requirements in Australia.

HLB MANN JUDD Chartered Accountants

Perth, Western Australia 28 February 2005 L DI GIALLONARDO Partner

Rule 4.2A.3

# Appendix 4D

# Half year report Half-Year ended 31 December 2004

Introduced 1/1/2003

refe	N or equivalent company rence 107 371 460					
55	107 37 1 400					
1.		Half year ended ('p				
	31 DECEMBER 2004	N/A				
2	Results for announcemen	t to the mark	cet			
\$A'	000					
.1	Revenues from ordinary activities		up/down	%	_	146
.2	Profit (loss) from ordinary activiti attributable to members	es after tax	up/down	%	to	(2,052)
		ibutable to	up/down	9/	to	(2,052)
.3	Net profit (loss) for the period attr members					<del></del>
		*	Amount pe	r security	Franke	d amount per
Pivid	members		Amount pe	r security  N/A¢	Franke	•
ivid	members  lends (distributions)	report only)	Amount pe		Franke	ecurity
oivid .4	members  ends (distributions)  Final dividend (Preliminary final	report only) ort only)	Amount pe	N/A¢	Franke	ecurity N/A¢
.3 Divide .4 .5	members  lends (distributions)  Final dividend (Preliminary final Interim dividend (Half yearly reported)  Record date for determining entit	report only) ort only) clements to the	N/A	N/A¢	Frankers	ecurity N/A¢ N/A¢

3. NTA backing		Current period	Previous corresponding Period
Net tangible assets p	er security	\$0.074	N/A

# 4. Control gained over entities having material effect

4.1	Name of entity (or group of entities)	R	Retmed Pty Ltd
4.2	Date of gain of control		1 July 2004
4.3	Consolidated profit (loss) from ordinary activities after tax		(\$931,924)
4.3			(\$57,692)

# Loss of control of entities having material effect

	ame of entity (or group of ntities)		N/A
4.2 Da	4.2 Date of loss of control		N/A
the	4.3 Consolidated profit (loss) from ordinary activities after tax of the controlled entity (or group of entities) since the date in the current period on which control was acquired		\$ N/A
en	Profit (loss) from ordinary activities after tax of the controlled entity (or group of entities) for the whole of the previous corresponding period		\$ N/A

# 5. Dividends / Distributions

Date the dividend (distribution) is payable	N/A
Amount per security of foreign source dividend	N/A¢

Tota	ı D	ahivi	nde	/Distr	·ihu	tions
1 1 1 1 2				, , , , , , , ,		

Ordinary securities	\$ N/A	
Preference securities	\$ N/A	

6. Dividend or distribution investment plans in ope	Dividend or distribution investment plans in operation:	
	N/A	
The last date(s) for receipt of election notices for the dividend or distribution reinvestment plans	N/A	

# 7. Details of aggregate share of profits (losses) of associates and joint venture entities

entities			
Name of associate/joint	N/A		
venture:			
Holding in entity	N/A %		
Group's share of associates' entities':	and joint venture	Current period \$A'000	Previous corresponding period - \$A'000
Profit (loss) from ordinary activity	ties before tax	N/A	N/A
Income tax on ordinary activities		N/A	N/A
Profit (loss) from ordinary acti	vities after tax	N/A	N/A
Extraordinary items net of tax		N/A	N/A
Net profit (loss)		N/A	N/A

8. Foreign Entities

Share of net profit (loss) of associates and joint

Adjustments

venture entities

N/A

N/A

N/A

N/A

# 9. All Entities

A description of Accounts subject to audit dispute or qualification:
N/A

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Rule 4.7B

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# **Appendix 4C**

# Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

Quarter ended ("current quarter")
31 December 2004

# Consolidated statement of cash flows

Cash flows related to operating activities		Current quarter \$A'000	Year to date \$A'000
1.1	Receipts from customers		
1.2	Payments for  (a) staff costs (b) advertising and marketing (c) research and development (d) leased assets (e) other working capital	(206) (23) (220) (209)	(396) (65) (538) - (463)
1.3	Dividends received	(207)	(103)
1.4	Interest and other items of a similar nature received	66	146
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Other (provide details if material)	41 - 2	
	(a) Consulting and professional services	(376)	(813)
	(b) Travel	(151)	(289)
	Net operating cash flows	(1,119)	(2,418)

<sup>+</sup> See chapter 19 for defined terms.

		Current quarter	Year to date
		\$A'000	\$A'000
1.8	Net operating cash flows (carried forward)	(1,119)	(2,418)
	Cash flows related to investing activities		
1.9	Payment for acquisition of:  (a) businesses (item 5)		
	(b) equity investments	(40)	(2,000)
	(c) intellectual property	(105)	(236)
	(d) physical non-current assets	(5)	(47)
1.10	(e) other non-current assets Proceeds from disposal of:	j	
1.10	(a) businesses (item 5)		
	(b) equity investments		
	(c) intellectual property		
	(d) physical non-current		
	assets (e) other non-current assets	ļ	
	(o) called from current assets		
1.11	Loans to other entities		
1.12	Loans repaid by other entities		
1.13	Other (provide details if material)  (a) Cash introduced on		112
	acquisition of controlled entity	-	112
	acquisition of continuous chinis,		
	Net investing cash flows	(150)	(2,171)
1.14	Total operating and investing cash flows		
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	82	101
1.16	Proceeds from sale of forfeited shares		
1.17	Proceeds from borrowings		
1.18 1.19	Repayment of borrowings Dividends paid		
1.20	Other (costs of capital raising)	(3)	(68)
	Net financing cash flows	79	33
		,,	
	Net increase (decrease) in cash held	(1,190)	(4,556)
1.21	Cash at beginning of quarter/year to date	6,563	9,929
1.22	Exchange rate adjustments to item 1.20	-,	
1.23	Cash at end of quarter	5,373	5,373

Appendix 4C Page 2 30/9/2001

<sup>+</sup> See chapter 19 for defined terms.

# Payments to directors of the entity and associates of the directors Payments to related entities of the entity and associates of the related entities

		Current quarter \$A'000	
1.24	Aggregate amount of payments to the parties included in item 1.2		
1.25	Aggregate amount of loans to the parties included in item 1.11		
1.26	Explanation necessary for an understanding of the transactions		
	\$77k - Executive Director's salaries		
	\$17k – Directors fees		
Non-cash financing and investing activities			
2.1	Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows		
	The allotment and issue of 22,420,000 ordinary fully paid shares at a deemed issue price of \$0.468 per share (deemed cost \$10,500,000) and 5,900,000 unquoted options at a nil price to the minority shareholders of Retmed Pty Ltd for the remaining 100% of the Company.		
2.2	Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest		
	N/A		

# Financing facilities available

Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

30/9/2001 Appendix 4C Page 3

<sup>+</sup> See chapter 19 for defined terms.

#### Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter \$A'000	Previous quarter \$A'000
4.1	Cash on hand and at bank	546	503
4.2	Deposits at call	4,827	6,060
4.3	Bank overdraft		
4.4	Other (provide details)		
	Total: cash at end of quarter (item 1.22)	5,373	6,563

# Acquisitions and disposals of business entities

		Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1	Name of entity	N/A	N/A
5.2	Place of incorporation or registration		
5.3	Consideration for acquisition or disposal		
5.4	Total net assets		
5.5	Nature of business		

# Compliance statement

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Stuart Usher
Joint CFO & Company Secretary

31 January 2005

Appendix 4C Page 4 30/9/2001

<sup>+</sup> See chapter 19 for defined terms.

## **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
- 2. The definitions in, and provisions of, AASB 1026: Statement of Cash Flows apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 itemised disclosure relating to acquisitions
  - 9.4 itemised disclosure relating to disposals
  - 12.1(a) policy for classification of cash items
  - 12.3 disclosure of restrictions on use of cash
  - 13.1 comparative information
- 3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

30/9/2001 Appendix 4C Page 5

<sup>+</sup> See chapter 19 for defined terms.



2 March 2005

The Manager Company Announcements Australian Stock Exchange 4<sup>th</sup> Floor 20 Bridge Street SYDNEY NSW 2000

Dear Sir

## Option holder letter

Please find attached a letter which has been distributed to option holders today.

Yours sincerely,

Dr. William J Ardrey IV Chief Executive Officer



1 March 2005

Dear Option holder,

# Convert Your RGAO Options Before 30 April to Receive a New Option

RGAO Option holders in Regenera Limited have until 30 April 2005 to convert their Options into ordinary shares at the conversion price of 75 cents to receive a **New** Option at no additional cost. The options are quoted on the ASX under the Code: RGAO and since listing have traded in a range of 5 cents (low) to 21 cents (high).

Attached is your customised 'Exercise of Option' Form which lists your current holding of options and the amount payable should you exercise your total holding. Payment must be received at Advanced Share Registry Services, PO Box 6283, East Perth, WA 6892, no later than 30th April 2005.

## What happens when I convert my option?

On receipt of your payment and completed Exercise of Option Form you will be sent a holding statement confirming the number of new Regenera shares that have been allotted on conversion of your options. These shares are tradeable immediately. In addition you will be issued with a new (free) option to replace the option you exercised. The terms of this new option are the same with the exception that the exercise price will be \$1.10 and the holder will not be entitled to the issue of any further options in the event the new option is exercised.

# Why is it good to convert your option before 30<sup>th</sup> April?

If you convert your option before 30<sup>th</sup> April 2005:

- You will receive a new (free) replacement option.
- You will be able to acquire a parcel of shares with no brokerage fees. If you were to buy a large parcel of shares on market your purchase price may be greater than 75 cents, whereas the conversion of the option guarantees your purchase price at 75 cents.
- The Company benefits from you converting your option because it is able to raise additional funds without paying broking fees and capital raising fees.

## What happens if I do not convert my option now?

The option that you currently hold remains valid but the terms associated with that option will change after the 30<sup>th</sup> April 2005.

From 1<sup>st</sup> May 2005 you will no longer be able to exercise your option at 75 cents, the new exercise price will be \$1.10 at anytime before 30<sup>th</sup> June 2008 and you will not be entitled to the issue of any further options (new options) in the event you exercise your option.

#### What will happen to the price of the option?

We are unable to speculate what may happen to the price of the option but three major factors influence the market price of an option.

- Current market price of the ordinary share
- The exercise price of the option
- The time value which defines the period during which the shares can be bought at the exercise price.

After the 30<sup>th</sup> April 2005, the existing quoted options and the new free options will have the same terms and conditions with an exercise price of \$1.10 per share and an expiry date of 30<sup>th</sup> June 2008. Application will be made to the ASX for the quotation of the new options on 1<sup>st</sup> May 2005 which will be quoted under the ASX Code: RGAO, the same code as the existing options.

If you require further information on how to go about converting your options into fully paid ordinary shares please contact the Joint Company Secretary Mr Stuart Usher on +61 (0) 8 9389 5933. Should you require an additional 'Exercise of Option Form' it will be available for download from the Company's web site at www.regenera.com.au .

Yours sincerely,

Dr William Ardrey Chief Executive Officer